IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

J.R., by and through his parents, DAVID REID and CORINNE REID, and DAVID REID and CORINNE REID, Individually

Plaintiffs,

v.

ADVANCED BIONICS, LLC, ADVANCED BIONICS CORPORATION, DOES 1-10 (intending to represent the Manufacturer(s) of the feedthru component for The Clarion S-Series C1.2 cochlear implant Bearing serial number 10062),

Defendants.

Civil Action No.
11-CV-0843 GLS/TWD

PLAINTIFFS' FIRST AMENDED COMPLAINT

Plaintiffs J.R., by and through his parents, David Reid and Corinne Reid, and David Reid and Corinne Reid individually (collectively "the Reid family") bring this action pursuant to applicable statutory and common law against Defendants Advanced Bionics Corporation, a California Corporation, and Advanced Bionics, LLC, a Delaware Limited Liability Company, and say for their Complaint as follows:

SUMMARY OF THE ACTION

1. On or about March 23, 2009, in the City of Syracuse, Onondaga County, New York, J.R. suffered from total bilateral deafness and was forced to undergo a lengthy and risky open-head surgery as a result of the failure of two Advanced Bionics HiRes 90k medical devices (individually, the "Device") recalled by their manufacturer, Advanced Bionics, because they

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contained a manufacturing defect in a component supplied by AstroSeal, Inc., and were, therefore, not in compliance with applicable federal law, including federal device manufacturing requirements.

2. Defendants violated the basic principal of biomedical engineering that moisture is to be avoided in electronic devices implanted in the human body. Advanced Bionics sold cochlear implants, medical devices used to provide a sense of sound to persons with profound hearing loss, that leaked. Advanced Bionics' specification for moisture content was 0.5%, yet J.R.'s failed devices contained moisture far in excess of the limit. Water entered J.R.'s Advanced Bionics' HiRes90k implants through a leak in AstroSeal manufactured components, causing device failure and requiring explantation surgery and other related damages.

3. The HiRes90k Devices placed in J.R.'s head were designed, manufactured, and sold in violation of federal law and in violation of Advanced Bionics' federally-approved device specifications. The devices contained a latent defect not disclosed to the Food and Drug Administration ("FDA"), were adulterated, breached Advanced Bionics' express and implied warranties, and were defective and unreasonably dangerous for their intended use. Defendants were negligent in the design, manufacture and labeling of the Device and the AstroSeal component meant to provide a hermetic (waterproof) seal. Defendants knew that their devices were failing at an alarming and unacceptable rate as a result of moisture intrusion, had been cited by the FDA for violating federal manufacturing regulations, and yet Defendants continued to produce defective devices knowing full well that it had not solved the moisture problems with its product. By October 2004 at the latest, Defendants knew the HiRes 90K was leaking at the feed-thru yet did not advise clinicians or patients of the defect.

4. The FDA filed an administrative enforcement action against Advanced Bionics and key employees for selling devices of the exact same type given to J.R. because those devices were not FDA approved for sale in the United States and were manufactured in violation of federal law. Advanced Bionics settled this FDA action, paying $1.1 million on behalf of the company and $75,000 on behalf of then-CEO Jeffrey Greiner, individually.

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5. Defendants are liable to the Reid family for all consequential damages incurred as a result of injuries to J.R. Defendants are liable for J.R.'s pain, suffering, temporary and permanent hearing loss, revision surgeries and punitive damages. Defendants are liable for any and all other damages sustained by the Reid family. The Reid family demands a trial by jury.

PARTIES

6. J.R. is a minor resident of Onondaga County, New York. Plaintiffs David Reid and Corinne Reid are adult residents of Onondaga County, New York.

7. Defendant ADVANCED BIONICS CORPORATION is a California Corporation with its principal place of business at 28515 Westinghouse Place, Valencia, CA 91355.

8. Defendant ADVANCED BIONICS, LLC, is a Delaware Limited Liability Company with its principal place of business at 12740 San Fernando Road, Sylmar, CA 91342. Advanced Bionics, LLC, has done and continues to do business as Advanced Bionics Corporation and is a corporate successor to prior entities using the name "Advanced Bionics" for all purposes relevant to this Complaint subject to all liabilities relative to this Complaint attributable to a prior entity known as Advanced Bionics Corporation, a Delaware Corporation and was present and doing business in the City of Syracuse, Onondaga County, New York.

9. At all relevant times, Defendants were engaged in the business of, or were a successor in interest to entities engaged in the business of researching, developing, formulating, testing, manufacturing, producing, distributing, marketing, promoting, packaging and selling hearing implant devices for use by individuals with hearing loss, including J.R.

VENUE

10. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a). The Plaintiffs are residents of the State of New York, and the Defendants are foreign corporations, with their principal places of business outside of the State of New York.

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11. The amount in controversy in this matter exceeds $75,000.00, exclusive of interest and costs.

12. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391(a) and (c). Defendants regularly solicit and engage in business and other persistent courses of conduct and derive substantial revenues from goods used and consumed in New York and/or for services rendered in New York.

13. Defendants derive substantial revenue in New York from interstate commerce.

14. Defendants' Devices were provided and/or prescribed to, purchased and consumed by Plaintiffs in the State of New York.

15. Defendants supplied, shipped, and delivered cochlear implant devices to the State of New York; solicited and serviced accounts in the State of New York, and contracted to supply cochlear implant devices in the State of New York, including for implantation in J.R.

16. Defendants knew their cochlear implants would end up in the State of New York and, if defective, would cause serious injury to the cochlear implant recipients in the State of New York, and they knew of J.R.

17. Defendant Advanced Bionics' listing of clinics and distributors include the following State of New York sites: Auditory Oral School of NY in Brooklyn, New York' Bassett Healthcare in Cooperstown, New York; Buffalo ENT Specialists in Buffalo, New York; Buffalo Hearing & Speech Center in Buffalo, New York; Capital Region Ear Institute in Slingerlands, New York; Capital Region Otolaryngology in Albany, New York; Central New York ENT Consultants in Syracuse, New York; Children's Hospital/Morgan Stanley Children's Hospital, New York Presbyterian Hospital in New York, New York; Columbia University Medical Center in New York, New York; ENT and Allergy Associates in New York, New York' Montefiore Medical Center in Bronx, New York; Mount Sinai Medical Center in New York, New York; New York Eye and Ear Infirmary Cochlear Implant Center in New York, New York; New York Institute of Technology in Old Wesbury, New York; North Shore Medical Group Mount Sinai School of Medicine in Huntington, New York; Northern Westchester Hospital

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Center The Balance Center in Mt. Kisco, New York; NYU Cochlear Implant Center in New York, New York; Rochester Institute of Technology/NTID in Rochester, New York; State University of NY at Stonybrook in East Setauket, New York; SUNY Downstate Medical Center in Brooklyn, New York; University ENT of Northeastern New York in Albany, New York; University Hospital at Syracuse in Syracuse, New York; University of Rochester/Strong Health Audiology in Rochester, New York; VA Medical Center – New York City in New York, New York; and Westchester Medical Center WIHD/Speech and Hearing Center in Valhalla, New York.

18. Defendant Advanced Bionics sponsored, funded, or organized continuing education seminars for speech-language pathologists and audiologists and provided manufacturer's representatives at these seminars in the State of New York.

19. Defendants provided sales literature to medical facilities, audiology clinics, and clinicians in the state of New York, that was in turn provided to Plaintiffs and relied upon in the Plaintiffs' decision to purchase the HiRes 90k cochlear implants, provided technical and warranty support directly to Plaintiffs, initiated direct e-mail and telephone contact with Plaintiffs after J.R.'s devices failed, and shipped a replacement cochlear implant to New York to replace J.R.'s defective unit.

20. Defendants sponsored, funded, or organized live seminars for consumers and provided manufacturer's representatives at these seminars in the State of New York.

21. Defendants created, sponsored, subsidized, funded and/or advertised a hearing health advocacy division named the Bionic Ear Association ("BEA"), with local Chapters located in Western New York and New York City.

22. The "BEA" is prominently listed on www.advancedbionics.com, which provides "BEA" information such as internet links, a listing of "BEA" Chapters nationwide, cochlear implant testimonials, an online community for cochlear implant recipients and their families and those considering a cochlear implant, solicitation of "BEA" mentors, a "BEA" events calendar,

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online chat capabilities, and a listing of "BEA" Regional Managers, including a Northeast Regional Manager that services the State of New York.

23. The New York "BEA" Chapters held regular events in the State of New York, such as picnics, meetings, and parties and advertised or otherwise listed such events on www.advancedbionics.com and in flyers showing the Advanced Bionics logo and copyright.

24. Upon information and belief, the "BEA" was created and promoted by Defendant Advanced Bionics in an effort to convince or persuade individuals, including the Reid family, to purchase cochlear implants.

25. Defendants committed tortious acts within New York by marketing, distributing, retailing and selling its HiRes 90k cochlear implants, dangerous and defective medical devices, to the Reid family, which proximately caused J.R.'s injuries.

26. Defendant Advanced Bionics employs a Northeast Regional Manager, a Northeast Territory Sales Manager, Sales Associates, and Manufacturer's Representatives, all of whom personally conduct business in the State of New York, including the delivery and sale of products designed by Advanced Bionics.

27. Defendants conducted regular clinical trials in the State of New York, including at the Columbia University Medical Center and the New York University Medical Center in New York, New York.

28. Defendants expected or reasonably should have expected that their tortious acts would have consequences in New York.

29. Jurisdiction is proper. Defendants regularly solicit and engage in business and other persistent courses of conduct and derive substantial revenues from goods used and consumed in New York and/or for services rendered in New York. This action is directly related to Defendants' business activities in New York.

30. Venue is proper as a substantial part of the conduct giving rise to Plaintiffs' damages occurred in Onondaga County, including the implantation of the defective devices, the

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subsequent failure of the devices, and removal surgery including hospitalization resulting from same.

31. Each Defendant is individually, as well as jointly and severally, liable to the Reid family for damages.

32. The limitations on liability set forth in CPLR § 1601 do not apply by reason of one or more of the exemptions set forth in CPLR §1602, including subsections 2, 7, and 11.

GENERAL ALLEGATIONS

I. Cochlear implants are prosthetic hearing devices.

33. A cochlear implant is a Class III medical prosthesis designed to enable profoundly deaf persons to "hear" by directly stimulating auditory nerves leading to the brain by means of an electrode array strategically positioned in the cochlea of the inner ear.

34. Unlike hearing aids, cochlear implants do not amplify sound; instead, a miniature computer/sound processor, worn outside the body, selectively processes sound into coded signals. Such signals are transmitted by wireless electromagnetic conduction to an implantable cochlear stimulator (ICS) that is surgically implanted in the patient's body.

35. The ICS receives these coded signals and interprets them using its sophisticated microelectronic architecture to send specialized patterns of electrical current to the electrodes inserted inside of the cochlea. Multiple electrodes along the length of the electrode array emit electrical currents in the form of electrical stimulation pulses to the surrounding hearing nerve receptors based on scientific knowledge that different parts of the cochlear are sensitive to different sound frequencies. Nerve fibers then send this information to the brain for central processing, interpretation, and perception as sound.

36. Cochlear implant surgery requires general anesthesia and often involves a procedure called a mastoidectomy, in which an incision is cut and an indent is drilled into the skull to allow the attachment of the implant. Once the implant is attached, the electrode array is inserted in the delicate coiled cochlea of the inner ear by making a hole called a cochleonstomy

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and inserting the electrode array and pushing it through as gently as possible to avoid trauma to the inner surfaces. Post-surgery vertigo and nausea are common. Paralysis of the facial nerves is a risk of surgery, as is tinnitus, bleeding, cerebrospinal fluid leak, damage to taste, and damage to the vestibular system. The patient also has risks of anesthesia including but not limited to death.

37. After surgery, initial programming of the external processor is not done until the incision has healed, which typically takes two to five weeks. At such initial stimulation and programming, the individual electrodes are programmed at appropriate threshold and amplitude levels based on the patient's response to stimulation which is then used to create an electrode "map." Once all of the electrodes are mapped, the processor is turned on and the cochlear implant patient can "hear." This programming process continues to be fine-tuned at later appointments throughout the first year with the external processor eventually being programmed with multiple maps for different auditory environments.

38. In normal hearing, the cochlea is stimulated by hundreds of thousands of hair cells. The stimulation of the cochlea through implanted electrodes is very different. Thus a cochlear implant demands a long rehabilitation period in which the cochlear implant recipient's brain must learn how to decode and recognize sound.

39. The perception of sound by cochlear implant users is very different from normal hearing. Cochlear implant patients who have lost their hearing often describe the initial stimulation as hearing tiny "buzzes" and "whistles" that had no relation to what they remembered as sound and felt that they would never be able to comprehend.

40. Gradually through aural rehabilitation and listening experience, the brain may learn to decode sound. Over time, some cochlear implant recipients learn to distinguish sounds well enough so that they can talk on the telephone through the cochlear implant or listen to TV without closed-captioning.

41. When a defective cochlear implant is replaced, the electrode array may not be re-implanted in the same position in the cochlea, leading to different threshold and amplitude settings. As a result, rather than starting off by "hearing" at the comprehension level where the

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defective implant failed, a cochlear implant patient may have to go through a second aural rehabilitation before the replacement implant functions at the same level as the first implant did.

42. There is no guarantee that a replacement cochlear implant will ever function at the same level as the first. In some cases, due to cochlea scarring or nerve damage from explant surgery, different electrode positioning, or other causes, a cochlear implant patient may not function as well with the replacement implant.

43. Different cochlear implant manufacturers use different sound strategies. Thus when a defective implant is replaced with a new device by a different cochlear implant manufacturer, an entire new sound system needs to be learned.

44. Bilateral implantation, in which cochlear implants are surgically implanted in both ears, is increasingly becoming a desirable option for young children. The reasoning is that bilateral sound assures that sound is processed through both sides of the brain, which enables the brain to mature and to learn to process bilateral information during a period where maximum brain plasticity and linguistic development occurs.

II. Moisture causes failure to cochlear implants.

45. Moisture is a well-known cause of failure of electronic circuits.

46. Moisture causes corrosion, dendrite growth, and other processes that damage electronic circuits and cause them to fail.

47. Implantable medical devices, such as cochlear implants, are exposed to more moisture than most electronic devices because the human body is a very wet and salty (saline) environment.

48. The human body is more than fifty percent (50%) water.

49. To function reliably electronic circuits inside cochlear implants should be clean, dry, and free of moisture.

50. Cochlear implants should remain dry and free of moisture vapor in excess of 0.5% to prevent harm to patients.

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51. It is critical that a cochlear implant not allow moisture in, or any toxic compound out.

52. The failure of a cochlear implant requires surgery to remove and replace the failed implant.

53. Revision surgery risks include damage to the cochlea, cerebro-spinal fluid leak, permanent loss of hearing, facial paralysis, bleeding, infection and other complications including risk of death.

54. A revision surgery to explant and replace a cochlear implant can cause harm to a patient.

55. Moisture inside a cochlear implant may have been sealed in during the manufacturing process, leaked in at some point afterwards (including after the device was implanted in a patient), or both.

56. There is no other way moisture can enter a device.

57. A variety of techniques exist to determine the effectiveness of a seal (whether the seal is water proof or hermetic) of microelectronic devices with designed internal cavities. A designed internal cavity is the void space inside the device.

58. A variety of techniques exist to determine the moisture content (for example, the percentage of water vapor) within sealed microelectronic devices with designed internal cavities.

59. Residual gas analysis ("RGA") is an analytical technique used primarily for hermeticity quality assurance and failure analysis purposes. In RGA, the test device is placed in a sealed chamber and punctured. The interior gases are sucked out and analyzed. The RGA can reveal, for example, the percentage of water vapor within a sealed medical device.

60. The RGA and other techniques to evaluate the hermeticity of a device may provide data to determine if, and why, a device leaked. Such techniques can also be used to determine if a device was properly assembled in the first place.

61. At all relevant times Advanced Bionics knew that federal law required its medical devices to be water proof, hermetically sealed, and without excessive moisture content.

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62. Device failure can occur in a cochlear implant when the percentage of moisture vapor in a device is greater than 0.5%.

III. Advanced Bionics' HiResolution Cochlear Implant.

63. Advanced Bionics manufactured and sold a cochlear implant system referred to as the "HiResolution Bionic Ear System." The HiResolution system was marketed as an improved version of Advanced Bionics' former "CLARION Multi-Strategy Cochlear Implant." It was marketed as the HiRes90k.

64. The implant component of the system was the implantable cochlear stimulator (the "ICS").

65. The ICS consisted of, among with other parts, a "can," a sealed titanium metal housing containing an electronic circuit, an electrode (an insulated wire) that goes into and stimulates the cochlea, and an antenna to receive signals from the external processor.

66. The ICS included a feed-thru (also referred to as a feed through or feedthru) assembly. The feed-thru is designed to keep moisture from entering the implant and connects the electronic circuit inside the implant to the electrode through a water and gas proof fitting.

67. Advanced Bionics has used two different feed-thru suppliers on its HiRes90k cochlear implant device: Pacific Aerospace & Electronics, Inc. ("PA&E") and AstroSeal.

68. Both suppliers were to provide interchangeable feed-thru assemblies meeting the same high standard of functionality and Advanced Bionics' specifications, including that the feed-thru provide a water proof and hermetic seal during the implant's anticipated 10-year life span.

69. Advanced Bionics added AstroSeal as a feed-thru supplier without receiving approval from FDA.

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IV. Federal Regulations

70. One method of removing a class III medical device from the market is a recall. A manufacturer should recall a product when that product is suspected of inflicting patient harm.

71. Under federal regulations, a "[r]ecall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 C.F.R. Part 7.3(g).

72. A device is deemed to be "adulterated" if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with federal regulations pursuant to 21 U.S.C. § 351 and 21 C.F.R. Part 820.1(c).

73. A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

74. Advanced Bionics is required to comply with applicable FDA regulations, including FDA regulations relating to records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of its medical devices.

75. Adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 C.F.R. Part 803.50.

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76. Manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. *See* 21 C.F.R. Part 803.52.

77. Manufacturers must report to the FDA in five business days after becoming aware that a medical device reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. Medical device reportable events require the manufacturer to conduct a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. *See* 21 C.F.R. Part 803.53

78. Device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 C.F.R. Part 806.10.

79. Pursuant to federal regulations, Current Good Manufacturing Practices ("CGMPs") require compliance with the following quality system regulations:

a. Manufacturers must meet design-control requirements, including without limitation, conducting design verification and validation to ensure that devices conform to defined use needs and intended uses;

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b. Manufacturers must establish purchasing controls to ensure that all purchased products, parts and components conform to specified requirements;

c. Manufacturers must meet quality standards in manufacturing and production;

d. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions;

e. Manufacturers must investigate the cause of nonconforming product and take corrective action to prevent recurrence;

f. Manufacturers are required to review and evaluate all complaints and determine whether an investigation is necessary;

g. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance.

See generally 21 C.F.R. Part 820.

80. The CGMPs required that Advanced Bionics sufficiently evaluate and select AstroSeal as a supplier of feed-thru assemblies on the basis of its ability to meet specified device requirements, including quality requirements, related to its intended long-term use in the human body. 21 C.F.R. Part 820.50(a).

81. The CGMPs required that Defendants adequately validate all cochlear implant devices by testing production lots under actual or simulated use conditions. 21 C.F.R. Part 820.30(g).

82. The CGMPs required Defendants to investigate the cause of moisture in its cochlear implants and to take corrective action to prevent reoccurrences and to investigate clinical complaints from patients reporting erratic or non-functioning implants.

83. As stated above, a manufacturer's failure to comply with CGMPs applicable to a device renders the device adulterated under the FDCA, 21 U.S.C. § 351(h); 21 C.F.R. Part

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820.1(c). Each introduction of an adulterated device into interstate commerce is a violation of the FDCA. 21 U.S.C. § 331(a).

84. A device is deemed adulterated if the methods used in, and the facilities and controls used for, its manufacture, packing, storage, and installation are not in conformity with CGMP requirements. Each introduction of an adulterated device into interstate commerce is a violation of federal law. 21 U.S.C. § 331(a).

V. Pre-Market Approval (PMA) Process.

85. FDA regulations require manufacturers to submit Pre-Market Approval Application ("PMA") supplements for changes that may affect the safety or effectiveness of a device, including "[t]he use of a different facility or establishment to manufacture" the device, and "[c]hanges in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device." 21 C.F.R. Part 814.39(a)(3) and (6). Such supplements are referred to as "180-day PMA supplements."

86. Any change in specifications of the materials used in manufacture requires a 180-day PMA supplement.

87. A manufacturer may make a change to a device without filing a PMA supplement **only** if the change does not affect the device's safety or effectiveness and the change is reported to FDA in post-approval periodic reports. 21 C.F.R. Part 814.39(b).

88. A feed-thru can affect the safety and/or effectiveness of a cochlear implant.

89. The former Director of Regulatory Affairs of Advanced Bionics (Kay Adair) testified in a deposition that a feedthru can affect the safety or effectiveness of a cochlear implant.

90. A device lacking necessary PMA approval (including approval of supplements) is deemed adulterated. 21 U.S.C. § 351(f)(1)(B).

91. Federal regulations require that a PMA supplement be submitted when unanticipated adverse effects increases in the incidence of anticipated adverse effects, or device

failures necessitate a labeling, manufacturing, or device modification. *See* 21 C.F.R. Part 814.39.

92. Advanced Bionics first received PMA approval to manufacture cochlear implants for adults in 1996. The HiRes 90k was not approved as a separate Class III device, but was approved in the Thirtieth PMA supplement submitted by Advanced Bionics on July 7, 2003.

93. The July 2003 PMA listed as a "Conditions of Approval" that before Advanced Bionics made any changes affecting the safety or effectiveness of a device, it would submit a PMA supplement for review and approval by the FDA. This requirement in the July 2003 PMA was in accordance with FDA rules and regulations stating the same. *See* 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39(a).

94. Defendants were well aware of the PMA Supplement requirement. Not only was this requirement listed in all of Advanced Bionics' previously approved PMAs, but in 2001, the FDA had issued a List of Inspectional Observations ("Form FDA-483") related to an on-site inspection of Advanced Bionics' Sylmar, California facility related to hermeticity failure in an earlier model. In this FDA Form 483, the FDA listed Advanced Bionic's failure to file PMA supplements for four separate testing, manufacturing process, and design changes as violations of FDA regulations.

95. As part of the July 2003 HiRes 90k PMA, the FDA approved of the design of the internal ICS of the HiRes 90k implant which was housed in a hermetically sealed (i.e. moisture-proof and airtight) titanium case attached to a critical component called the feed-thru assembly. As already alleged above, the feed-thru is the component that conducts electrical signals from the hermetically (waterproof) sealed part of the ICS to the electrode array.

96. The feed-thru, as a critical component to the Advanced Bionics' HiRes 90k, performs the critical task of connecting the internal electronic circuit board to the implanted electrodes through a series of pins which form the electrical path to the electrode array.

97. Equally important, the feed-thru assembly is designed to prevent internal body moisture from entering the implant by creating a hermetically (i.e.) water-proof and moisture

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proof barrier between the ICS internal circuitry and the electrodes. As such, the FDA approved specifications for the HiRes 90k which included the following:

a. that the HiRes 90k device would be "hermetically sealed" to prevent water intrusion;

b. that the HiRes 90k device would have a leak rate of less than 1 x 10^{-9} cc- atm/s of helium;

c. that the HiRes 90k device be 100% tested at the time of manufacture for hermeticity;

d. that the HiRes 90k device would contain no more than 0.500% (5,000 ppm) moisture; and

e. that the HiRes 90k and Clarion 1.2 devices be sealed with an inert gas mixture, 25% helium and 75% argon.

98. During the PMA approval process, Advanced Bionics submitted design data and documents relating only to the use of PA&E a/k/a Vendor A as the supplier of the critical feed-thru component.

99. After receiving the July 2003 PMA approval for the HiRes 90k based on only PA&E data, Advanced Bionic began using AstroSeal a/k/a Vendor B as a supplier of the HiRes 90k feed-thru.

100. The specifications of the AstroSeal feed-thru differed from the PA&E in at least nine ways, including but not limited to:

a. the composition of AstroSeal's glass seal was different, resulting in a different rate of thermal expansion in the glass;

b. there was a different mechanical configuration to support the ceramic bead of the AstroSeal feed-thru;

c. AstroSeal's feed-thru had a shorter glass seal;

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d. the glass for the AstroSeal feed-thru was fired through a vacuum bake for a different length of time and at a different temperature than was approved in the July 2003 PMA; and

e. the thickness of the oxide layer was different.

101. Keith McLain, the Head of Quality at Advanced Bionics, wrote a report that outlined differences in the PA&E (vendor A) and AstroSeal (vendor B) feed-thru.

102. The change in using AstroSeal as a feed-thru supplier affected the safety and effectiveness of the HiRes 90k, yet Advanced Bionics neither filed a 180-Day PMA Supplement nor a 30-Day Notice under 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39. AstroSeal was not mentioned in any post approval periodic report under 21 C.F.R. Part 814.39(b).

103. Within six months from the time that Advanced Bionics started using AstroSeal as a feed-thru supplier, Advanced Bionics became aware of excess moisture in HiRes 90k implants implanted in the human body after such implants were returned to Advanced Bionics after being removed from patients' bodies either for medical reasons (such as implant rejection, infection, or other medical complications) or because of device failure.

104. This awareness occurred, in part, because the FDA required that Advanced Bionics perform specific testing, including hermeticity tests, on returned devices to understand the reason for device failure and to improve device reliability.

105. For those still functioning devices removed for medical reasons that showed elevated moisture levels, Advanced Bionics did not report to the FDA that the moisture exceeded the FDA limit. Nor did Advanced Bionics do any further analysis on these devices to determine where the moisture was coming from, despite Advanced Bionics' knowledge that moisture could be expected to damage the sophisticated internal electronic circuitry of its HiRes 90K devices. Advanced Bionics amended Failure Analysis Reports to remove language that devices with high moisture failed a hermeticity test.

106. Advanced Bionics still did not file a 180-Day PMA Supplement or a 30-Day Notice informing the FDA of its use of AstroSeal as a feed-thru assembly supplier. Nor did

Advanced Bionics inform the FDA of its use of AstroSeal as a feedthru assembly supplier in any post-approval periodic report filed under 21 C.F.R. §814.39(b).

VI. Device Reporting.

107. Pursuant to federal regulations, manufacturers must report adverse events associated with a medical device to the FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to serious injury, or that a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. 21 C.F.R. Part 803.50.

108. Pursuant to federal regulations, Advanced Bionics must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 C.F.R. Part 803.52.

109. Pursuant to federal regulations, manufacturers must report to the FDA within five (5) business days after becoming aware that an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. 21 C.F.R. Part 803.53. An MDR reportable event is, among other things, an event that makes a manufacturer aware that a device marketed by the manufacturer has malfunctioned or may have caused or contributed to a death or serious injury. 21 C.F.R. Part 803.3.

110. Similarly, device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device,

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or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. 21 C.F.R. Part 806.10.

111. Upon information and belief, pursuant to its approved PMA, Advanced Bionics must submit an "Adverse Reaction Report" or "Device Defect Report " within 10 days after Advanced Bionic receives or has knowledge of information concerning any "adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device " and (a) has not been addressed by the device's labeling or (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

112. Advanced Bionics must submit an "Adverse Reaction Report" or "Device Defect Report" pursuant to 21 C.F.R. Part 814.82(a)(9) within 10 days after Advanced Bionic receives or has knowledge of information concerning any "adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device" and (a) has not been addressed by the device's labeling or (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

113. Advanced Bionics' failure to meet the above-referenced federal requirements applicable to medical devices and Advanced Bionics' other acts and omissions as described herein directly and proximately caused the subject device to be in violation of federal law, adulterated, misbranded, unfit for sale, defective and unreasonably dangerous and the proximate and legal cause of harm to the Reid family.

114. The Reid family's state law claims against Advanced Bionics are premised, *inter alia*, on Advanced Bionics' violation of federal regulations, and are parallel state law

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requirements that do not conflict with and are not in addition to or different from federal requirements.

115. AstroSeal, as a manufacturer of components or parts of finished devices, was not subject to federal CGMP requirements set forth in the quality system regulation, 21 C.F.R. Part 820, although they were "encouraged to use appropriate provisions of the CGMP requirements as guidance," pursuant to 21 C.F.R. Part 820.1(a).

VII. The FDA required that the ICS be hermetically sealed and free of moisture.

116. Advanced Bionics' federally approved manufacturing specification required that the Device be "hermetically sealed" to prevent water intrusion.

117. Advanced Bionics federally approved manufacturing specification required that the Device have a leak rate of less than 1 x 10-9 cc-atm/s of helium.

118. Advanced Bionics' federally approved manufacturing specification required that the Device be 100% tested at the time of manufacture for hermeticity.

119. Advanced Bionics' federally approved manufacturing specification required that the Device be sealed with an inert gas mixture, 25% helium and 75% argon.

120. Advanced Bionics admitted in the PMA that the Device was designed to last for a lifetime.

121. Defendants expressly warranted the HiRes90k Device for 10 years.

122. To have any reasonable chance of operating over the anticipated 10-year life span, the Device must remain hermetically sealed and free of excessive moisture.

123. Advanced Bionics was required to comply with the CGMP, 21 C.F.R. Part 820.

124. The CGMP required that Advanced Bionics sufficiently evaluate and select AstroSeal as a supplier of feed-thru assemblies on the basis of its ability to meet specified Device requirements, as required by 21 C.F.R. Part 820.50(a).

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125. The CGMP required that Advanced Bionics adequately validate Devices containing the AstroSeal feed-thru assemblies by testing production lots under actual or simulated use conditions, as required by 21 C.F.R. Part 820.30(g).

126. Advanced Bionics is and was required to qualify all critical components at the component level of a cochlear implant prior to marketing the cochlear implant to the public.

127. Advanced Bionics is and was required to qualify the HiRes 90k device at the device level using all critical components prior to marketing the cochlear implant to the public.

128. Advanced Bionics is and was required to test the HiRes 90k device in an environment that mimics the environment in which the device is to be implanted, i.e. the human body prior to marketing the cochlear implant to the public.

129. Advanced Bionics is and was required to conduct simulated life testing of the HiRes 90k prior to marketing the cochlear implant to the public.

130. The helium leak test does not mimic the human body.

131. Keith McLain, as Head of Quality at Advanced Bionics, testified that the helium leak test does not mimic the human body.

132. Advanced Bionics is and was required to validate the HiRes 90k using all critical components prior to marketing the cochlear implant to the public.

133. Advanced Bionics is responsible for qualification of a medical device and its critical components, not the FDA.

134. Advanced Bionics is responsible for validation of a medical device, not the FDA.

135. Advanced Bionics is responsible for supplier quality and audits, not the FDA.

136. Advanced Bionics is responsible for performing failure analysis testing on returned (explanted) devices, not the FDA.

137. Advanced Bionics is responsible for tracking and trending reasons for device failure, not the FDA.

138. Advanced Bionics is responsible for determining the root cause of device failure, not the FDA.

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139. Patient safety is paramount to profit at a medical device company.

140. It is reckless for a medical device company to place profits over patient safety.

VIII. Knowledge of Device Leaks From 2003 to 2004.

141. In approximately July of 2003, Advanced Bionics commercially released the HiResolution cochlear implant in the United States.

142. Prior to July 2003, Advanced Bionics did not run accelerated life cycle testing on the HiRes90k.

143. Prior to July 2003, Advanced Bionics did not run the same qualification tests on the AstroSeal feedthru that were run on the PA&E feedthru.

144. Prior to July 2003, Advanced Bionics did not test the HiRes90k containing an AstroSeal feedthru under actual or simulated use conditions.

145. Prior to July 2003, Advanced Bionics did not run an immersion test by attempting to force liquid water into an AstroSeal feedthru under actual or simulated use conditions.

146. Prior to July 2003, Advanced Bionics had a total deficiency in implant life testing.

147. Prior to July 2003, Advanced Bionics submitted no document to the FDA concerning the HiRes90k that mentioned AstroSeal as a component supplier.

148. Per Kay Adair, former Head of Regulatory Affairs to Advanced Bionics, the failure to notify the FDA of the use of AstroSeal was a "mistake."

149. Advanced Bionics nevertheless began manufacturing and marketing for sale in July 2003 to the general public, doctors and hospitals the HiRes90k cochlear implant.

150. Advanced Bionics received returned HiRes 90k implants including through September 2004.

151. Implants were removed and returned for medical reasons (for example, infection or other medical complications) or because of device failure.

152. Advanced Bionics performed hermeticity and moisture content testing on returned implants.

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153. Advanced Bionics' reasons for testing returned implants included to understand the reason for device failure, to improve device reliability, and to comply with the CGMP and other applicable federal regulations applicable to medical devices.

154. On February 12, 2004, Advanced Bionics performed an RGA on an explanted device. The RGA showed that the device had moisture in excess of 0.500%.

155. On April 14, 2004, Advanced Bionics performed an RGA on an explanted device. The RGA showed that the Device had moisture in excess of 0.500%.

156. Advanced Bionics opened an investigation to understand the reason(s) for excessive moisture inside the device.

157. In June 2004, Advanced Bionics employee Josh Polack visited Pernicka Corporation.

158. During the June 2004 Pernicka visit, or shortly thereafter, Advanced Bionics learned of at least two explants with RGA moisture/vapor percentage greater than 0.500%. In one instance, the moisture/vapor content in the device was 32%.

159. By June 25, 2004, a total of fourteen (14) devices were tested, eight (8) of which (57%) contained moisture in excess of 0.500% In one instance the moisture/vapor content in the device was 30%.

160. Advanced Bionics knew by at least June 25, 2004 that its devices contained moisture above specifications at an excessive and unacceptable rate and that patients were, as a result, experiencing device failure at an excessive rate and suffering hearing loss and surgery to remove the failed devices.

161. By July 2004, Advanced Bionics performed testing on its auditory manufacturing bake out ovens, and said testing confirmed said ovens were functional and effective.

162. As of the summer of 2004, Advanced Bionics attributed the root cause of moisture in most explanted devices to leaks after manufacture – the failure of the implant to maintain an effective hermetic seal.

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163. In 2004, there was a known moisture problem at Advanced Bionics involving the HiRes90k including the following:

a. On or about August 10, 2004, Defendants were notified that the FDA would perform a for-cause inspection of its manufacturing facility.

b. In August/September 2004, former majority shareholder Al Mann ordered quality assurance employees to stop testing returned devices to keep the number of moisture failures low while the FDA was on site.

c. In October 2004, a former manufacturing employee named Phil Segel wrote in an email that it was known Advanced Bionics cochlear implants were leaking at the feedthru.

d. The same month, one of the designers to the HiRes90k wrote that the investigation into moisture leaking was being handled "poorly." The same person commented that he had tried to convey his feelings before but had run into an "impenetrable wall of resistance" at the company management level.

e. At the same time, other employees (including Nancy Brehm) were emailing about moisture failures in the HiRes90k as a result of leaking.

f. In December 2004, an engineer (Josh Polack) charged with investigating moisture failures in the HiRes90k wrote a memo to the file advising that data pointed to cochlear implants were leaking at the feedthru.

g. Kay Adair, the former head of Regulatory Affairs at Advanced Bionics, ordered that the HiRes90k leaking be discussed "in person" and not in writing.

h. This was a known tactic at Advanced Bionics, as former Head of Quality Keith McLain discussed in 2006 the need to stop "minimizing the paper trail."

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i. Defendants did not reveal to doctors, audiologists, patients or potential recipients of HiRes90k devices that there was known leaking at the feedthru in October, November or December 2004. Advanced Bionics knowingly misrepresented to clinicians and patients that an internal moisture level of below 5% was harmless when in fact its specification for maximum moisture was .5%.

j. The Reid family was never told there was known leaking in the HiRes90k device, as reported in October through December 2004 by Advanced Bionics employees.

k. Had Defendants told the Reid family that Advanced Bionics cochlear implants were leaking, the Reid family would not have chosen the HiRes90k.

l. Defendants knew that patients would not choose its products if they revealed there was a problem with devices leaking, so they intentionally concealed this knowledge from physicians and patients/potential patients like the Reid family.

m. The actions of Defendants, as asserted below, were intentional, reckless, malicious and fraudulent.

IX Advanced Bionics and the 2004 FDA inspection.

164. On August 10, 2004, the FDA contacted Defendants to announce they would be initiating an inspection on August 25, 2004.

165. The inspection was in regards to device reliability concerns, especially hermeticity.

166. Loss of hermeticity in a cochlear implant can cause harm to cochlear implant recipients.

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167. No one from Defendants notified the Reid family or the Reid family's medical providers that an inspection had taken place because of device reliability concerns with the HiRes 90k in August / September 2004.

168. No one from Defendants notified the Reid family or the Reid family's medical providers that the FDA had "device reliability concerns, especially hermeticity" with Advanced Bionics' cochlear implants before J.R. received the Device.

169. The FDA conducted an on-site inspection of Advanced Bionics' Sylmar, California facility on or about August 25 to September 15, 2004.

170. At this time, the FDA determined that an excessive moisture problem existed with the HiRes 90K.

171. Advanced Bionics no longer manufactured the earlier Clarion models at the time of the August-September 2004 inspection.

172. As of August 25, 2004, the FDA still did not know that Defendants were using AstroSeal as a supplier of the feedthru assembly on the HiRes90k.

173. On September 15, 2004, the FDA issued a Form FDA-483 identifying serious non-conformities and weaknesses in Defendants' quality system that required improvement.

174. The FDA identified twenty-three (23) observations of federal regulations that an inspector deemed the company was not in compliance with via the Form FDA-483.

175. The FDA Form 483 specifically states that the cause of moisture in HiRes90k units has not been determined.

176. It was the responsibility of Defendants, not the FDA, to determine the cause of moisture in HiRes90k units.

X. Advanced Bionics issued its first Device recall in September of 2004.

177. On September 27, 2004, as a result of the FDA inspection, Defendants initiated a Class II Recall of all of its un-implanted CLARION and HiResolution Devices, Recall Number

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Z-0046-05, due to the "potential presence of moisture in the internal circuitry, which can cause the device to stop functioning."

178. The FDA forced Defendants to enact the September 27, 2004 recall. The fact that the recall was "forced" rather than voluntary has been admitted in deposition by the former CEO as well as in a Shareholders' report.

179. On September 29, 2004, Advanced Bionics sent a letter to HiRes 90K, Clarion 1.2, and Clarion II implant users explaining that moisture had been found on the internal circuitry of removed implants and that their implants "could stop working prematurely" if their implant was affected by this moisture problem. In its letter Advanced Bionics stated that it was recalling unimplanted products for testing. Advanced Bionics further acknowledged that sudden sensations of pain or discomfort, sudden loud noises or popping sounds, intermittent or complete loss of sound were signs that a HiRes 90K might be failing. In the letter Advanced Bionics claimed that its clinics had "a simple and quick way to test whether [an implant] is fully functional."

180. Defendants suspended shipment of new devices until November 8, 2004.

181. From September 27, 2004 until November 8, 2004 at the latest, Defendants investigated the purported reasons for HiRes90k devices being returned with high moisture.

182. As part of this process, Defendants investigated the bake-out ovens used in the manufacturing and made enhancements to the bake-out process.

183. All improvements and/or enhancements to the vacuum bake-out process were completed by November 1, 2004.

XI. The FDA found that Advanced Bionics' Devices were adulterated.

184. On February 1, 2005, the FDA issued Advanced Bionics a "Warning Letter" identifying eighteen (18) "significant deviations" from federal regulations in the "manufacturing, packaging, storage or installation" of medical Devices. A copy of the Warning Letter is attached as Ex. A.

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185. The FDA reported to Advanced Bionics that its inspection "disclosed that your [cochlear implant] devices are adulterated" within the meaning of Section 501(h) of the Federal Food, Drug and Cosmetic Act.

186. The FDA reported that Advanced Bionics was in violation of the CGMP regulations for medical devices set forth in the quality system regulation, specified in 21 C.F.R. Part 820.

187. In specific, the FDA detailed eighteen (18) deviations where the "methods used in, or the facilities or controls used for manufacturing, packaging, storage or installation" were "not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices as set forth in specific federal regulations." The noted deviations in the Warning Letter included, but were not limited to, Advanced Bionics':

a. failure to conduct management reviews with sufficient frequency as required by 21 C.F.R. Part 820.20(c), even though Advanced Bionics was aware that a significant manufacturing deficiency, moisture in HiRes 90K devices, was occurring;

b. failure to establish procedures for conducting quality audits and failure to conduct such audits to assure that Advanced Bionics' quality system was in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 C.F.R. Part 820.22;

c. failure to establish procedures for identifying training needs and to ensure that all personnel were adequately trained to perform their assigned responsibilities, as required by 21 C.F.R. Part 820.25(b), including that there was "inadequate knowledge regarding how [RGA] results could be used to determine if a device was hermetically sealed with water within the device at the time of

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manufacture or if the water entered the device as a result of a loss of hermeticity";

d. failure to document the 0.500% (5,000 ppm) "water content limit for the [HiRes 90K]" in a design input document as required in 21 C.F.R. Part 820.30(c);

e. failure of design verification to confirm that design output meets design input requirements as required by 21 C.F.R. Part 820.30(f), including that "there was no design verification and validation for the HiRes 90K product to meet the water content limit of less than 0.500% (5,000 ppm)";

f. failure to perform a risk analysis, as required by 21 C.F.R. Part 820.30(g), in that risk analysis was performed using single point fault conditions, which did not consider that loss of hermeticity or moisture trapped in a sealed device could result in multi-point failure in the implant;

g. failure to adequately validate manufacturing processes as required by 21 C.F.R. Part 820.75(a);

h. failure to establish and maintain a procedure for monitoring and control of process parameters for validated processes or to revalidate when changes or process deviations occur as required by 21 C.F.R. Part 820.75(b) & (c), especially related to the vacuum bake procedures;

i. failure to develop, conduct, control or monitor product processes to ensure that a device conforms to its specifications, as required by 21 C.F.R. Part 820.70(a), including a lack of monitoring and recording of vacuum pressure to ensure that vacuum level was maintained

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during the vacuum baking process to remove water/moisture prior to sealing;

j. failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch met acceptance criteria as required by 21 C.F.R. Part 820.80(d) including that Advanced Bionics' finished devices were not screened for gross leakage and there was no verification that the proper vacuum pressure was used;

k. failure to investigate the causes of nonconformities to product, process, and quality, or to identify the actions needed to correct and prevent such reoccurrences as required under 21 C.F.R. Part 820.100(a) (2) & (3) including the failure to adequately analyze explants removed for medical reasons to determine whether any electronic circuit board damage might have resulted from moisture damage that had not yet caused device failure;

l. failure to ensure that information related to quality problems or nonconforming product was disseminated to those directly responsible for ensuring quality of product or of such problems as required by 21 C.F.R. Part 820.100(a)(6), including that all available information related to device failures was not forwarded to the FDA as updates to the MDR; and

m. failure to comply with the PMA, including that the FDA was not informed that moisture was found in six out of eleven (55%) explanted devices that were still functioning and removed for medical reasons such as infection.

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188. The FDA reported to Advanced Bionics that "[u]ntil you have adequately demonstrated that you have corrected the violations . . . we continue to believe that the violations still pose a significant risk to public health."

189. The FDA directed that Advanced Bionics take "prompt action to correct these deviations" and that failure to do so may result in "seizure, injunction, and/or civil penalties."

190. The Letter also stated that "the specific violations noted in this letter . . . may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system" and that Advanced Bionics (not the FDA) was "responsible for determining and investigating the causes of the violations identified by the FDA."

191. In February 2005, the same month that the FDA issued its Warning Letter, auditory division president James (Jim) Miller wrote that HiRes 90k device failures "continue to occur at an alarming rate." See Email of James Miller (Ex. B).

192. Failures of HiRes90k devices using an AstroSeal feedthru continued throughout 2005.

193. Advanced Bionics still continued using AstroSeal as a feedthru supplier even though Advanced Bionics knew that no qualification test plan had been carried out to ensure that AstroSeal implants were in compliance with its intended use in the human body.

194. On or before March 2005, Defendants were aware that post-2004 recall HiRes 90K devices were failing and had high levels of moisture, yet it did not recall the current model HiRes 90K or inform the FDA of its use of AstroSeal as a feedthru supplier, even though Defendants were aware of serious quality issues with AstroSeal feedthrus.

XII. Internal audits found serious ongoing problems at Advanced Bionics.

195. Internal audits found serious ongoing quality problems at Advanced Bionics in 2004, 2005 and January-February 2006.

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196. Shortly after the FDA Warning Letter, Boston Scientific, the corporate parent of Advanced Bionics at the time with a principal place of business in Natick, Massachusetts, performed an internal investigation and audit of quality control at Advanced Bionics.

197. The audit discovered seven (7) major non-conformities and many uncorrected issues remaining from the 2004 Form 483 observations issued by the FDA.

198. In February of 2006, Boston Scientific contracted with an independent quality auditor, Quality Hub, to do an onsite audit of Advanced Bionics to verify the adequacy and completeness of Advanced Bionics corrective actions related to the 2004 Form 483 and the 2005 Warning Letter observations.

199. Specifically, Quality Hub arrived at the Advanced Bionics facility on February 21, 2006. The same day of Quality Hub's arrival, Advanced Bionics instituted corrective action to address the long-standing problem of leakage in the HiRes 90K cochlear implant including those in J.R.'s head.

200. The Quality Hub audit uncovered numerous deficiencies at Advanced Bionics. Advanced Bionics has admitted this fact.

201. Defendants failed to timely correct deviations noted by the FDA and by their internal auditors.

202. At all relevant times, Advanced Bionics remained out of compliance with federal requirements.

203. Advanced Bionics knew that device failures continued to occur in 2005 and 2006 at an alarming rate as a result of moisture inside the devices.

204. Defendants knew that the manufacturing process and quality changes they had implemented in 2004 and 2005 had not solved the moisture problem. Facts supporting the allegation include:

a. In October 2004, Phil Segel admitted devices were leaking at the feed-thru.

b. By November 1, 2004, all "fixes" to the bake-out oven were complete.

c. In December 2004, Josh Polack wrote that the evidence pointed to HiRes 90K devices leaking at the feed-thru.

d. Advanced Bionics did not pull its devices off the market in October, November or December 2004 despite corporate employees admitting that devices were leaking.

e. In February 2005, the president of the auditory division admitted devices were continuing to fail at an alarming rate.

f. Advanced Bionics still did not stop shipping the device.

g. In March 2005, Advanced Bionics received a HiRes 90K manufactured after the "fix" to the bake-out oven which was found to contain high moisture.

h. Advanced Bionics did not stop shipping its devices after it received this device.

i. Advanced Bionics received another "post-fix" HiRes 90K with high moisture in July 2005.

j. Advanced Bionics employee Alex Guttierez admitted that two out of specification devices set a trend.

k. In 2010, Advanced Bionics opened CAPA 210 after only two devices were returned out of specification.

l. In 2010, Advanced Bionics recalled after only two devices were returned out of specifications.

m. Unlike 2010, Advanced Bionics did not recall, stop shipment or open a CAPA for high moisture in July 2005, despite the trend of high moisture failures.

n. Advanced Bionics continued to receive devices with high moisture from August 2005 to January 2006.

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o. Advanced Bionics did not recall, stop shipment or open a CAPA for high moisture from August 2005 to January 2006.

p. In October 2005, Exponent advised Advanced Bionics that the odds it was manufacturing devices with sealed-in moisture was 1 in 10,000.

q. The Exponent report proved it was scientifically and statistically impossible to have sealed moisture in the devices manufactured after 11/1/04 that were returned with high moisture.

r. Advanced Bionics still did not recall, stop shipment or open a CAPA until 2/21/06.

205. Advanced Bionics recklessly, maliciously, and outrageously continued to market and sell cochlear implants in 2003, 2004, 2005 and early 2006 despite knowing that the devices had a moisture problem, having repeatedly been cited by the FDA for violations of federal regulations, including the CGMP, and yet Advanced Bionics failed (1) to properly test, qualify and validate the HiRes 90k device using an AstroSeal feed-thru, (2) to disclose the use of AstroSeal to the FDA and (3) to identify the root cause of the moisture problem and solve it in time to prevent J.R. from receiving a leaky Device that failed because of water intrusion.

XIII. Advanced Bionics Recalls Again In March 2006

206. On March 8, 2006, Advanced Bionics initiated two Class II recalls of all unimplanted HiRes90k cochlear implants containing feed-thru assemblies manufactured by AstroSeal, Recall Number Z-0759-06 for Model number CI-1400-2H and Recall Number Z-0758-06 for Model Number CI-1400-01.

207. Advanced Bionics initiated the recall because it belatedly acknowledged that HiRes90k devices containing the AstroSeal feed-thru were causing premature device failure and temporary and permanent hearing loss, pain, and suffering to patients and requiring surgery to remove and replace defective implants. Advanced Bionics also initiated the recall because the

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devices containing the AstroSeal feed-thru were out of compliance with federal requirements and the CGMP.

208. On March 15, 2006, Advanced Bionics admitted to the FDA that it had not previously disclosed the use of AstroSeal as a feedthru supplier in the HiRes90k.

209. Devices containing the AstroSeal feed-thru were adulterated, misbranded, and non-compliant with the company's own standards and FDA-approved specifications.

210. Advanced Bionics determined that moisture was not entering its implants during its manufacturing process, but instead, that moisture was leaking into the device through a defective feed-thru assembly manufactured by AstroSeal after the devices had been shipped and implanted in patients.

211. Advanced Bionics determined that the feed-thru manufactured by AstroSeal failed to reliably maintain a hermetic seal resulting in moisture content inside the devices above the company's 0.500% specification.

212. The defective AstroSeal feed-thru, according to Advanced Bionics, came to light after the product reached market and was not included or referenced in any manner in connection with the company's filings with the FDA.

213. Advanced Bionics failed to include any warning or labeling to the effect that its devices were not hermetically sealed and could leak after implementation in the human head.

214. Instead of the inert argon and helium gas that was supposed to be present inside the devices, defective AstroSeal feed-thrus contained moisture vapor.

215. The AstroSeal feed-thru, according to Advanced Bionics, "was not designed and built to effectively keep moisture out."

216. The AstroSeal feed-thru, according to Advanced Bionics, "did not meet our standards."

217. According to Advanced Bionics' Summer 2007 Auditory Reliability Report, 79.8% of Devices containing the Astro-Seal feed-thru were functional after 3 years. This figure

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has continued to fall. As of June 1, 2012, over 33% of all HiRes 90K devices with AstroSeal feed-thrus have failed.

218. For a Device warranted to last 10 years, failure of 20% of the Devices containing the AstroSeal feed-thru after 3 years as a result of moisture intrusion is an outrageous and catastrophic failure rate not approved by FDA and unacceptable by any standard of reliability, including Advanced Bionics' own standard.

219. By contrast, according to Advanced Bionics, its devices manufactured with a PA&E feed-thru have a failure rate of 1.5% after 3 years.

220. Advanced Bionics had information on the problem with the AstroSeal feed-thru assembly prior to March of 2006, but failed to timely notify the FDA and the medical community and patients and failed to take appropriate action to prevent harm to patients receiving the device.

221. There was at Advanced Bionics a program known as the Earn Out Program, a formula by which shares of stock in Advanced Bionics were purchased by Boston Scientific:

a. In the spring of 2004, Al Mann, on behalf of Advanced Bionics shareholders, began to market Advanced Bionics for sale to a third party.

b. In June 2004, Boston Scientific and Advanced Bionics reached a deal whereby Boston Scientific would purchase Advanced Bionics stock.

c. Shareholders were offered two means for payment of their stock: (1) a cash payout or (2) future payments plus a smaller cash payoff, with the future payments benchmarked on several factors including the number of cochlear implants shipped. (the "Earn Out")

d. There was no quality benchmark to the Earn Out program, so if a cochlear implant was returned as defective, there would not be a credit against a device that previously was counted toward the Earn Out benchmarks.

e. Employees over the course of the Earn Out were paid millions of dollars for the sale of defective Advanced Bionics HiRes90k units.

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f. By the admission of the Defendant Advanced Bionics, at the very least $64 million dollars in bonuses were paid on the sale of cochlear implants, i.e. the device that was deemed adulterated by the FDA in February 2005 and in 2007.

g. It is believed that payments were much higher than $64 million and that indeed hundreds of millions of dollars were paid in bonuses to Advanced Bionics shareholders.

h. Following the March 2006 recall, Advanced Bionics shareholders were not asked to refund earn out bonus payments and pay those sums of money to the many injured by the defective HiRes90k.

i. In fact, Boston Scientific believes that Advanced Bionics employees delayed recalling the HiRes90k until March 2006 so the shareholders could receive their bonus payments in February 2006 in the Earn Out program.

222. The Devices containing AstroSeal feed-thru assemblies were defective, negligent, unreasonably dangerous, and not in compliance with any applicable standard or regulation, including FDA-approved device manufacturing specifications and CGMP regulations promulgated by the FDA.

XIV. FDA's February 2007 Inspection

223. The FDA conducted an additional on-site inspection on February 20-27, 2007, which focused on Advanced Bionics' activities related to the March 8, 2006 recall. During the inspection, the FDA investigators discussed with Advanced Bionics three separate violations of the required PMA supplementation for changes to the HiRes 90K, including the failure to seek approval for the changes to the feedthru assemblies supplied by AstroSeal and failure to test HiRes90k units under actual or simulated use conditions before sale to the public.

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224. FDA learned that Advanced Bionics had not performed all of the FDA required testing before using AstroSeal as a feedthru vendor even though Advanced Bionics had conducted some of these tests for the PA&E feed-thru.

225. FDA found that Advanced Bionics had qualified AstroSeal as a supplier for the feedthru component based on helium leak testing, but did not conduct (1) hydrostatic pressure testing, (2) corrosion (soak) testing, or (3) simulated use life testing in an environment that simulated the human body, all of which involved immersion of the devices in saline solution similar to that of the human body, and did not conduct functional electrical testing to assess performance under actual stimulation conditions.

226. The helium leak test used by Advanced Bionics was a modified version of an acceptable helium leak test. Further, the helium leak test does not simulate the human body.

XV. FDA files an enforcement action against Advanced Bionics for violating federal law.

227. As the result of the 2007 inspection, the FDA filed a complaint in November 2007 against Advanced Bionics and its President and Co-CEO Jeffrey H. Greiner ("CEO Greiner") seeking administrative penalties related to Advanced Bionics' violation of the FDCA and its implanting regulations. The FDA amended its Complaint on March 17, 2008. See Amended FDA Complaint (Ex. C).

228. The amended complaint sought a $2.2 million penalty against Advanced Bionics for violating federal law, including the CGMP standards and failure to notify the FDA of a change in an outside supplier of the feed-thru component to Astro-Seal, thereby exposing recipients of the device to unnecessary health risks.

229. Specifically as to the FDA civil monetary penalty action:

a. The FDA announced that the device poses a "public health risk due to excessive moisture, exposing patients to the risk of device failure, possible surgery, and the potential for additional hearing loss."

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b. According to the FDA, Advanced Bionics CGMP violations include "the failure to sufficiently evaluate and select a new vendor as the supplier of a critical Device component and the failure to adequately validate the continued safety and effectiveness of the hearing aid by testing lots under actual or simulated use when the unapproved vendor's component was used."

c. According to the FDA, "Advanced Bionics shipped hearing aids in violation of the law between January 2005 and July 2006."

d. The FDA found that the design criteria and specifications of the AstroSeal feedthru components were materially different than the design criteria and specifications submitted to the FDA, thus constituting a violation of federal law.

e. The FDA further found that qualifying AstroSeal only on the basis of helium leak testing and not the hydrostatic pressure testing, corrosion soak testing, or functional soak testing to access performance under actual stimulation parameters, constituted a violation of federal law.

f. The FDA found that HiRes 90K devices containing Astro-Seal feedthrus were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) in that the HiRes 90k implants with an AstroSeal feed-thru did not have the required premarket approval for Class III devices "because changes were made that affected the safety and effectiveness" of the device when AstroSeal was used as a feedthru supplier, and yet Advanced Bionics did not file either a 180-Day PMA Supplement or 30-Day Notice under 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39.

g. The FDA further alleged that Advanced Bionics had violated the CGMP requirements in that the methods used in, and the facilities and controls used for, manufacturing, packaging, storage, and installation were not in

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conformity with CGMP requirements for Class III medical devices as set forth in the Quality System Regulation at 21 C.F.R. Part 820, including, but not limited to, Advanced Bionics:

1. failed to sufficiently evaluate and select AstroSeal as a feedthru supplier on the basis of ability to meet specified device requirements, as required by 21 C.F.R. Part 820.50a(a);
2. failed to adequate validate devices containing AstroSeal feedthrus by testing production lots under actual or simulated use conditions, as required by 21 C.F.R. Part 820.30.

h. The FDA stated that HiRes 90K devices containing the AstroSeal feedthrus constituted a public health risk because the excessive moisture exposed patients in whom the device was implanted to the risk of device failure, and the associated risks of surgical intervention, including anesthesia, meningitis, and permanent neurological damage.

i. The FDA also found that excess moisture also could lead to direct current leakage, which could result in permanent injury to the auditory nerve and loss of hearing.

230. Shortly after a third amended Complaint was filed by the FDA on July 7, 2008, the FDA and the Advanced Bionics settled the Administrative Action with Advanced Bionics agreeing to pay a $1.1 million fine, which is the maximum fine allowed in an administrative action. CEO Greiner agreed to pay a $75,000 fine personally.

XVI. Cochlear Implant Manufacturers Owe A Duty to Recipients

231. A cochlear implant manufacturer owes a duty to cochlear implant recipients to manufacture a cochlear implant device that is safe and effective.

232. The failure of a cochlear implant manufacturer to manufacture a cochlear implant device that is safe and effective can cause harm to a cochlear implant recipient.

233. A cochlear implant manufacturer must never needlessly endanger the safety of a cochlear implant recipient.

234. A cochlear implant must be tested under actual or simulated use conditions before the device is marketed to the public.

235. The failure to test a cochlear implant under actual or simulated use conditions before a device is marketed to the public can cause harm to the cochlear implant recipient.

236. A cochlear implant manufacturer must qualify a cochlear implant using all critical components prior to the device being marketed to the public.

237. The failure to qualify a cochlear implant using all critical components prior to the device being marketed to the public can cause harm to the cochlear implant recipient.

238. A cochlear implant manufacturer must strive to not cause harm to the cochlear implant recipient.

239. A cochlear implant manufacturer must run accelerated life cycle testing of a cochlear implant prior to marketing the device to the public.

240. The failure to run accelerated life cycle testing on a cochlear implant prior to marketing the device to the public could cause harm to the cochlear implant recipient.

241. A cochlear implant manufacturer must investigate the cause of moisture inside a returned cochlear implant.

242. The failure to investigate the cause of moisture inside a returned cochlear implant can cause harm to a cochlear implant recipient.

243. If there is more than one way to test a cochlear implant for moisture intrusion, a cochlear implant manufacturer should choose the test that results in a safer cochlear implant.

244. The failure to select a test that results in a safer cochlear implant can cause harm to the cochlear implant recipient.

245. A cochlear implant manufacturer must never allow a foreseeable danger to exist in a cochlear implant.

246. A cochlear implant manufacturer is not allowed to sacrifice safety for profits.

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247. The shareholders of a company must never choose personal financial gain over the safety of an implantable medical device.

248. A medical device company should run a test, no matter the cost, if it will confirm an implantable medical device is safe and effective for the intended user.

249. A cochlear implant manufacturer should not manufacture a defective cochlear implant.

250. A defective cochlear implant can cause harm to the cochlear implant recipient.

XVII. Plaintiff received a defective Device containing an AstroSeal component.

251. The Reid family, after being assured that Advanced Bionics cochlear implants were safe and effective, elected to proceed with implantation.

252. J.R. was implanted with an Advanced Bionics Clarion S-Series C1.2 cochlear device on June 16, 1999, serial number 10062. J.R. was 22 months old.

253. Beginning in 2002, J.R. began to experience intermittent problems with his C1.2 implant. J.R., as a four year old child, was unable to articulate the problems with the device. J.R. complained of discomfort, overly loud sensations, static noises, and pain or shocking caused by the implant. J.R. began to refuse to wear the external processor, resulting in a continued inability to hear. In an attempt to alleviate the pain, J.R.'s audiologist reduced the output of the device nearly to a level where J.R. could no longer hear.

254. As a result of these problems, J.R.'s parents and teachers reported concern that he was beginning to regress in hearing and speech and that J.R. would refuse to wear the external processor.

255. J.R. was implanted with an Advanced Bionics HiRes90k cochlear implant on September 3, 2004 in Syracuse, New York, serial number 222265. This was J.R.'s second Advanced Bionics implant, and the first in the left ear.

256. J.R.'s HiRes90k device implanted in the left ear contained an AstroSeal feedthru.

257. J.R.'s Advanced Bionics Clarion S-Series C1.2 cochlear implant, implanted in J.R.'s right ear, was deemed to be defective.

258. J.R. was physically seen by Advanced Bionics representatives – B. Foster on or about February 13, 2004 in Syracuse, New York and Katherine Melone on March 9, 2005 in Syracuse, New York – who failed to detect or discover the defective nature of J.R.'s cochlear implant.

259. Neither B. Foster nor Katherine Malone informed the Reid family that HiRes90k devices "continue to fail at an alarming rate."

260. Neither B. Foster nor Katherine Malone informed the Reid family that HiRes90k devices with an AstroSeal feedthru were being sold in violation of FDA regulations.

261. J.R. underwent an open-head explantation surgery for the C1.2 cochlear implant on September 7, 2005 in Syracuse, New York. This required general anesthesia and subjected J.R. to the stress and emotional pain associated with the surgery, the physical pain associated with the surgery, and recovery from the surgery.

262. J.R. was implanted with an Advanced Bionics HiRes90k cochlear implant on September 7, 2005 in Syracuse, New York, serial number 301531. This was J.R.'s third Advanced Bionics implant, and the second in the right ear. The implantation occurred shortly after the C1.2 device was explanted.

263. J.R.'s HiRes90k device implanted in the right ear contained an AstroSeal feedthru.

264. Beginning in 2007, J.R. began to experience intermittent problems with both of his Advanced Bionics HiRes90k cochlear implants and began to refuse to and could not wear the external equipment. Because of the defective nature of the cochlear implant devices, he complained of discomfort, including intermittent shorting of the implants, that the sound was too loud, and that the processors were uncomfortable.

265. Due to the problems J.R. was experiencing with his Advanced Bionics HiRes90k cochlear implants, he underwent a battery of testing by Advanced Bionics, which confirmed the

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devices were outside of specification, and Advanced Bionics recommended bilateral replacement.

266. Because of the defective nature of the cochlear implant devices, in Syracuse, New York on March 23, 2009, J.R.'s Advanced Bionics HiRes 90k cochlear implants behind his left and right ears were explanted. Based on the repeated defective nature of the Advanced Bionics cochlear implants, a total lack of trust in Advanced Bionics, and after suffering multiple failed implants as a result of a defective component, J.R.'s family opted not to proceed with another Advanced Bionics product. Instead, he was implanted behind both ears with a Cochlear Nucleus Freedom with Contour Advance Electrone, a cochlear implant that is not manufactured by Advanced Bionics. This required J.R. to endure another open-head surgery under general anesthesia. He was also subjected to the stress and emotional pain associated with the unnecessary surgery, the physical pain associated with the surgery, and the recovery from the surgery.

267. Defendants failed to warn the Reid family, the Reid family's surgeon, or the medical facility at which J.R.'s operation was performed that the HiRes90k Device was manufactured and marketed using AstroSeal as a feed-thru supplier without FDA approval, that J.R. was receiving untested, invalidated and unqualified devices with an AstroSeal feed-thrus, or that J.R. was receiving "adulterated," "misbranded" and experimental devices as that term is defined by FDA regulations.

268. Defendants did not advise the Reid family, the Reid family's surgeon, or the medical facility at which J.R.'s operation was performed that Al Mann, the Co-Chief Executive Officer and majority owner of Defendant Advanced Bionics, had instructed that testing of Advanced Bionics returned devices stop in August / September 2004 until after the FDA left the facility.

269. The Reid family was not told that the HiRes90k devices implanted were not tested under actual or simulated use conditions before the device was marketed in July 2003.

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270. The Reid family was not informed that an Advanced Bionics engineer advised before J.R. was implanted that there was not enough data to determine whether AstroSeal feedthrus were reliable.

271. The Reid family was not informed that the HiRes90k with an AstroSeal feedthru was not subjected to the same qualification tests as the HiRes90k with a PA&E feedthru.

272. The Reid family was not informed that Advanced Bionics knew at the latest by October 2004 that HiRes90k devices were leaking at the feedthru.

273. The RGA testing on J.R.'s failed right C1.2 device revealed the device had .7013% water/vapor. The Failure Analysis Report for his device concluded the device was leaking: "The device had excessive moisture that exceeded the RGA test limit of 0.5%. Dye penetrant testing revealed zyglo intrusion at one of the feedthru pins."

274. On or about May 18, 2009, Advanced Bionics issued a Failure Analysis Report on J.R.'s two explanted Advanced Bionics HiRes 90k cochlear implants.

275. The RGA testing on J.R.'s failed left HiRes90k device revealed the device had a staggering 50.6845% water/vapor at the time of testing. Advanced Bionics confirmed in a Failure Analysis Report that J.R.'s device failed because of leaking caused by the "Astroseal Feedthru Issue."

276. The RGA testing on J.R.'s failed right HiRes90k device revealed the device had a staggering 23.2839% water/vapor at the time of testing. Advanced Bionics confirmed in a Failure Analysis Report that J.R.'s device failed because of leaking caused by the "Astroseal Feedthru Issue."

277. The Reid family had no role in the damage and/or destruction of the Device as it was not in the Reid family's possession, custody or control at the time of damage by Advanced Bionics and/or the company's agents.

278. J.R. was required to endure unnecessary and severe pain and suffering related to his multiple unnecessary open-head surgeries. He was required to "learn" to hear all over again on two separate occasions as a result of the device failures, which resulted in loss of enjoyment

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of life, regression in speech and hearing, difficulties in learning, emotional distress, and mental agony.

FIRST CAUSE OF ACTION

NEGLIGENCE

279. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

280. At all relevant times, Defendants had a duty and continued to owe a duty to the Reid family to: (a) provide a safe and effective Devices, both initially and upon reimplantation, in design and manufacture, (b) notify the FDA of design flaws, (c) manufacture and test the Devices properly in compliance with applicable regulations and FDA-approved specifications, and (d) notify the Reid family of the defective nature of the Devices and that the Devices contained an unapproved critical component, were prone to leaking, and were not tested prior to initial marketing in an environment that simulated the end use environment.

281. Defendants breached their duty of reasonable care to the Reid family by incorporating a defect into the design of the Devices, by failing to manufacture the Devices within the standard of care, by failing to properly test, validate and qualify the feed-thru and Devices and by failing to notify the Reid family of the risk that the Devices would not be hermetically sealed and free of excessive moisture, thereby causing the Reid family's injuries.

282. Defendants breached their duty of reasonable care to the Reid family by manufacturing and assembling the Device in such a manner that they were not hermetically sealed, contained moisture, allowed moisture to leak in after the Device has been implanted, and would, therefore, short circuit, corrode, or otherwise malfunction and expose patients, including J.R., to loss of hearing, unnecessary surgery, to life-threatening physical trauma, pain and suffering and developmental loss or delay.

283. Defendants breached their duty of reasonable care to the Reid family by failing to notify and warn the FDA, J.R.'s treating physicians, Plaintiff and the public at the earliest possible date of known design or manufacturing defects in the Device.

284. Defendants breached their duty of reasonable care to the Reid family by failing to exercise due care under the circumstances, including but not limited to failure to timely recall.

285. Defendants breached their duty by failing to qualify and validate the HiRes 90k with an AstroSeal feed-thru.

286. Defendants breached their duty by failing to test the HiRes 90k with an AstroSeal feed-thru under actual or simulated use conditions before commencement of marketing of the Device.

287. Defendants breached their duty by not performing life cycle testing on the HiRes 90k with an AstroSeal feed-thru before implantation in J.R.'s head.

288. Advanced Bionics breached its duty to Plaintiffs in at least the following ways:

a. Advanced Bionics' deviated from the FDA-approved design and manufacturing specifications for the HiRes 90K by, among other things, using a feedthru component manufactured by Astro Seal rather than a feedthru component manufactured by PA&E, including, but not limited to, the violations described in the 2001 FDA Form-483, 2004 FDA Form-483, the 2005 Warning Letter, the 2007 FDA Form-483 and 2007 and 2008 FDA Complaints;

b. Advanced Bionics failed to obtain supplemental PMA approval for use of the Astro Seal feedthru component through a 180-Day PMA Supplement or 30-Day Notice under 21 U.S.C. 360e(d)(6)(A)(i); 21 C.F.R. §814.39, including, but not limited to, the violations described above and the federal violations described in the 2004 FDA Form-483, the 2005 Warning Letter, the 2007 FDA Form-483 and 2007 and 2008 FDA Complaints.

c. Advanced Bionics failed to comply with the conditions of approval specified in the FDA PMA approving the HiRes 90K and earlier PMAs including, without limitation, the requirement that Advanced Bionics obtain supplemental approval prior to making any change that could affect the safety and effectiveness of Advanced Bionics cochlear implant devices;

d. Advanced Bionics failed to comply with applicable CGMPs in the manufacture of Advanced Bionics cochlear implant devices, including, but not limited to, the violations described in the 2001 FDA Form-483, 2004 FDA Form-483, the 2005 Warning Letter, the 2007 FDA Form-483 and 2007 and 2008 FDA Complaints;

e. Advanced Bionics failed to adequately ensure that devices conformed to user's needs as required by the FDA CGMPs;

f. Advanced Bionics failed to comply with applicable adverse event reporting requirements involving Advanced Bionics cochlear implant devices, including, but not limited to, the violations described in the 2001 FDA Form-483, 2004 FDA Form-483, the 2005 Warning Letter, and 2 the 2007 FDA Form-483, 2007 and 2008 FDA Complaints;

g. Advanced Bionics failed to investigate the cause of nonconformities relating to products, processes, and the quality system, including, inter alia, conducting trend analysis to identify nonconformities and premature device failures;

h. Advanced Bionics failed to ensure that Advanced Bionics cochlear implant devices contained no more than 0.500% (5,000 ppm) moisture as required by the FDA and/or its PMA and failed to ensure that no cracks existed or would develop in the conductive epoxy of its feedthru assemblies under expected use conditions in the human body;

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i. Advanced Bionics failed to sufficiently evaluate and select Astro Seal as a supplier of feedthru assemblies on the basis of its ability to meet specified device requirements as required by the FDA CGMPs;

j. Advanced Bionics failed to adequately validate Advanced Bionics cochlear implant devices by testing production lots under actual or simulated use conditions; and

k. Advanced Bionics concealed "life cycle" test results that were secretly started after July 2003, which showed a fifty percent (50%) failure rate.

289. As a direct and proximate result of the defects, J.R. was forced to endure multiple explant and re-implantation surgeries that caused him severe physical, mental, and emotional pain and suffering, including but not limited to pain and suffering at the site of the implants, shocking sensations, facial tics, excessive loudness, volume sensitivity, startling with sound, static noises, intermittent shorting of the implants, and pain with coupling of the implants; periods of prolonged deafness; isolation; electrocution; interruption of his learning, including but not limited to regression in speech performance, speech recognition, speech awareness, and communication skills; refusal to wear his external processors; frustration resulting in behavioral issues; and misdiagnosis as suffering from "bipolar disorder" when he was actually suffering physical pain and harm that he was unable to verbalize due to his tender age. This has negatively affected J.R.'s ability to learn and to communicate with family and friends, caused him to experience social isolation, and has made social environments, including the classroom, more difficult to endure. He was required to "learn" to hear all over again on two separate occasions as a result of the device failures, which resulted in loss of enjoyment of life, regression in speech and hearing, difficulties in learning, emotional distress, and mental agony.

290. As a direct and proximate result of Defendants' wrongful conduct, including failure to comply with applicable FDA requirements and FDA-approved Device specifications and Civil Code Section 1714(a), the Reid family and J.R. have sustained and will continue to sustain severe physical injuries, hearing loss, unnecessary surgery, severe emotional distress,

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economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial.

291. As a direct and proximate result of Defendants' wrongful conduct, including failure to comply with applicable industry standards, the Reid family and J.R. have sustained and will continue to sustain severe physical injuries, hearing loss, unnecessary surgery, severe emotional distress, economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial.

SECOND CAUSE OF ACTION

NEGLIGENCE PER SE

292. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

293. Defendants have an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, distribution, advertising, preparing for use, warning of the risks and dangers of the Device.

294. Defendants were negligent in at least the following ways, although there are additional means by which the Defendants were negligent for violation of federal statutory and regulatory law.

295. Advanced Bionics deviated from the FDA-approved design and manufacturing specifications for the HiRes 90k by, among other things, using a feed-thru component manufactured by AstroSeal rather than a feed-thru component manufactured by PA&E, including the violations described in the 2004 and 2005 FDA Form-483s and 2007 FDA Amended Complaint.

296. Advanced Bionics failed to obtain supplemental PMA approval for use of the AstroSeal feed-thru component through a 180-Day PMA Supplement or 30-Day Notice under 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39, including to the violations described in the 2004 and 2005 FDA Form-483s and 2007 FDA Amended Complaint.

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297. Advanced Bionics failed to comply with the conditions of approval specified in the FDA PMA approving the HiRes 90k and earlier PMAs including, without limitation, the requirement that Advanced Bionics obtain supplemental approval prior to making any change that could affect the safety and effectiveness of a device.

298. Advanced Bionics failed to comply with applicable CGMPs in the manufacture of the HiRes 90k including, but not limited to, the violations described in the 2004/2005 FDA Form 483s, 2005 FDA Warning Letter; and the 2007 FDA Amended Complaint.

299. Advanced Bionics failed to comply with applicable adverse event reporting requirements involving the HiRes 90k, including, but not limited to, the violations described in the 2005 FDA Warning Letter; and the 2007 FDA Amended Complaint.

300. Advanced Bionics failed to ensure that HiRes 90k devices contained no more than 0.500% (5,000 ppm) moisture as required by its PMA.

301. Advanced Bionics failed to sufficiently evaluate and select AstroSeal as a supplier of feed-thru assemblies on the basis of its ability to meet specified device requirements as required by the FDA CGMPs.

302. Advanced Bionics failed to adequately validate the HiRes 90k devices by testing production lots under actual or simulated use conditions.

303. The manufacture of the HiRes90k was performed in violation of the Code of Federal Regulations and the federal statutory law.

304. Overall, Defendants failed to comply with Federal law in at least the following ways:

a. Defendants deviated from the FDA-approved design and manufacturing specifications for the HiRes 90K by, among other things, using a feedthru component manufactured by Astro Seal rather than a feedthru component manufactured by PA&E, including, but not limited to, the violations described in the 2004 FDA Form-483, the 2005 Warning Letter, the 2007 FDA Form-483 and 2007 and 2008 FDA Complaints;

b. Defendants failed to obtain supplemental PMA approval for use of the Astro Seal feedthru component through a 180-Day PMA Supplement or 30-Day Notice under 21 U.S.C. 360e(d)(6)(A)(i); 21 C.F.R. §814.39, including, but not limited to, the violations described in the 2004 FDA Form-483, the 2005 Warning Letter, the 2007 FDA Form-483 and 2007 and 2008 FDA Complaints.

c. Defendants failed to comply with the conditions of approval specified in the FDA PMA approving the HiRes 90K and earlier PMAs including, without limitation, the requirement that Advanced Bionics obtain supplemental approval prior to making any change that could affect the safety and effectiveness of Advanced Bionics cochlear implant devices;

d. Defendants failed to comply with applicable CGMPs in the manufacture of Advanced Bionics HiRes 90K cochlear implant devices, including, but not limited to, the violations described in the 2004 FDA Form-483, the 2005 Warning Letter, and the 2007 FDA Form-483 and 2007 and 2008 FDA Complaints;

e. Defendants failed to comply with applicable adverse event reporting requirements involving Advanced Bionics HiRes 90K cochlear implant devices, including, but not limited to, the violations described in the 2004 FDA Form-483, the 2005 Warning Letter, the 2007 FDA Form-483 and 2007 and 2008 FDA Complaints;

f. Defendants failed to ensure that Advanced Bionics HiRes 90K cochlear implant devices contained no more than 0.500% (5,000 ppm) moisture as required by the FDA and/or its PMA and failed to ensure that no cracks existed or would develop in the conductive epoxy of its feedthru assemblies under expected use conditions in the human body;

g. Advanced Bionics failed to sufficiently evaluate and select Astro Seal as a supplier of feedthru assemblies on the basis of its ability to meet specified device requirements as required by the FDA CGMPs;

h. Defendants failed to adequately validate Advanced Bionics HiRes 90K cochlear implant devices by testing production lots under actual or simulated use conditions;

i. Defendants failed to adequately track Advanced Bionics HiRes 90K cochlear implant devices to the final user or patient, causing delays in notifications regarding serious problems and defects with the devices.

305. Defendants' acts constitute violations of the following applicable federal statutes:

a. 21 U.S.C. 360e(d)(6)(A)(i);

b. 21 C.F.R. 814.39;

c. 21 C.F.R. 814.39(a);

d. 21 C.F.R. Part 820;

e. 21 C.F.R. Part 821;

f. 21 C.F.R. 820.20;

g. 21 C.F.R. 820.20-c;

h. 21 C.F.R. 820.22;

i. 21 C.F.R. 820.25(b);

j. 21 C.F.R. 820.30(b);

k. 21 C.F.R. 820.30(f);

l. 21 C.F.R. 820.30(g);

m. 21 C.F.R. 820.30-c;

n. 21 C.F.R. 820.50;

o. 21 C.F.R. 820.70(a);

p. 21 C.F.R. 820.75(a);

q. 21 C.F.R. 820.75(b);

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r. 21 C.F.R. 820.75-c;

s. 21 C.F.R. 820.80;

t. 21 C.F.R. 820.80(d);

u. 21 C.F.R. 820.100;

v. 21 C.F.R. 820.100(a)(1);

w. 21 C.F.R. 820.100(a)(2);

x. 21 C.F.R. 820.100(a)(3);

y. 21 C.F.R. 820.100(a)(6);

z. 21 C.F.R. 820.100(b);

aa. 21 C.F.R. 820.198;

bb. 21 C.F.R. 820.250(a);

cc. FDCA 501(h);

dd. FDCA 519.

306. Defendants' acts constitute an adulteration, misbranding, or both, as defined by the Federal FDCA, 21 U.S.C. §§ 331(a) and 333(a)(2) and applicable FDA regulations, and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom and from parallel state law requirements, under the theory of negligence per se.

307. The Reid family, as a purchaser of the Defendants' Device, is within the class of persons the statutes and regulations described above are designed to protect, and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

308. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiff for all general, special, and equitable relief to which Plaintiff is entitled by law.

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THIRD CAUSE OF ACTION

STRICT LIABILITY – DESIGN DEFECT

309. Plaintiff hereby incorporates all preceding paragraphs of Plaintiff's complaint as if fully set forth herein.

310. At all times relevant to this action, Defendants were engaged in the business of designing, manufacturing, producing, inspecting, testing, packaging, warranting, distributing, selling, supplying, and otherwise placing cochlear implant devices into the stream of commerce. The Clarion S-Series C1.2 and HiRes 90k devices were manufactured and used for the purpose of allowing individuals with complete or severe hearing impairment to experience sound, and other related uses.

311. Upon information and belief, at all times relevant to this action, Defendants "Does" 1-10 were engaged in the business of designing, manufacturing, producing, inspecting, testing, packaging, warranting, distributing, selling, supplying, and otherwise placing their feedthru components for cochlear implant devices into the stream of commerce.

312. The Clarion S-Series C1.2 cochlear implant devices, including the device implanted into J.R. on June 16, 1999, was defective at the time it left the hands of the Defendants in that it was not reasonably safe and a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner.

313. The HiRes 90k cochlear implant devices, including the devices implanted into J.R. on September 3, 2004 and September 7, 2005, were defective at the time they left the hands of the Defendants in that they were not reasonably safe and a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner.

314. The Clarion S-Series C1.2 and HiRes 90k cochlear implant devices, at the time they left the hands of the Defendants, were so likely to harm the recipients that a reasonable manufacturer or person who had actual knowledge of their potential for producing injury would conclude that they should not have been placed into the stream of commerce in that fashion.

315. In addition, the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices failed to conform to and/or fell below consumer expectations and/or failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

316. As a direct and proximate result of the defectively designed cochlear implant devices, Plaintiffs suffered serious injuries as herein alleged.

317. As a direct and proximate result of Defendants' wrongful conduct, J.R. has sustained and will continue to sustain severe physical injuries and/or death, hearing loss, unnecessary surgery, severe emotional distress, economic losses, and other damages for which J.R. is entitled to recover in an amount to be proven at trial.

318. Defendants Advanced Bionics had specific knowledge of the unusually high rate of device failures, that the devices were not tested or validated in accordance with federal law, and that the devices were adulterated, prior to the date that J.R.'s implants were surgically implanted. Defendants Advanced Bionics' conduct, as set forth therein, was done with fraud and/or malice, and in conscious, willful, and reckless disregard of J.R's health, safety, and welfare. Thus, Plaintiffs are entitled to recover punitive damages.

FOURTH CAUSE OF ACTION

STRICT LIABILITY – MANUFACTURING DEFECT

319. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

320. The Devices were defectively manufactured because the foreseeable risks of mechanical malfunction and failure using a device that leaks water outweighs the benefits associated with the device, particularly given that correct manufacturing technology allows medical device manufacturers to produce devices that do not leak to an excessive degree.

321. The devices were manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.* (hereinafter "FDCA") and applicable FDA

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regulations. The facilities or controls used by Defendants in the manufacture, packing, storage, or installation of the devices were not in conformity with applicable regulations and FDA-approved specifications for the device or the CGMP requirements set forth in FDA's quality system regulations, 21 C.F.R. Part 820.

322. Defendants knew or should have known of the manufacturing defect and the risk of serious bodily injury that exceeded the benefits associated with the design of the Device.

323. Furthermore, the Device and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

324. The Device is inherently dangerous for its intended use due to design and/or manufacturing defect and improper functioning. Defendants are, therefore, strictly liable.

325. The following is true in terms of the date of manufacture of J.R.'s Devices:

a. At all times relevant to this action, Defendants knew that J.R.'s Devices, including its components, would be purchased by healthcare providers and/or patients for the purpose of surgical implantation in the human body.

b. At all times relevant to this action, Defendants knew that J.R.'s Devices would be used without inspection for defects.

c. J.R.'s Devices were manufactured in a manner violative of the FDCA and applicable FDA regulations.

d. The cochlear implants failed to conform to required device specifications approved by the FDA and failed to comply with other applicable federal laws and regulations, including, but not limited to, the violations described in the 2001 FDA Form 483, the 2004/2007 FDA Form 483s, 2005 FDA Warning Letter, and the 2007 FDA Amended Complaint.

e. The lack of compliance with the FDCA and applicable FDA laws and regulations caused the Device to be unsafe for its intended use and instead exposed the users of the Device to serious injury by reason of defects in their manufacture, testing, components, and constituents. Such failures

include, but are not limited to, the failure of Defendants to properly guard and protect users of the HiRes 90k from the defective manufacture of the device.

f. J.R. used the HiRes 90k device in a manner that was reasonably foreseeable to Defendants.

g. The failure of the HiRes 90k device due to defects, while it was implanted in J.R.'s skull, was the direct and proximate cause of serious injuries to J.R. as herein alleged.

326. As a direct and proximate result of Defendants' wrongful conduct, J.R. has sustained and will continue to sustain severe physical injuries and/or death, hearing loss, unnecessary surgery, severe emotional distress, economic losses, and other damages for which J.R. is entitled to recover in an amount to be proven at trial.

327. Defendants are liable to the Reid family for all general, special, and equitable relief to which the Reid family is entitled by law.

FIFTH CAUSE OF ACTION

STRICT LIABILITY – FAILURE TO WARN

328. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiff's Complaint as it set forth fully herein.

329. Defendants Advanced Bionics sold and distributed the Clarion S-Series C1.2 and HiRes90k cochlear implant devices in an unreasonably dangerous and defective condition in violation of applicable federal laws and regulations and without adequate warnings of the risks and dangers posed by such adulterated devices.

330. At all times relevant to this action, Defendants Advanced Bionics had a duty to warn the Reid Family of dangerous defects in the Clarion S-Series C1.2 and HiRes 90k devices

because, *inter alia*, Defendants Advanced Bionics knew, or reasonably should have known, that as a result of its violations of federal laws and regulations, including, but not limited to, the violations described in the 2001 FDA Form 483, 2004/2005 FDA Form 483s, 2005 FDA Warning Letter, and the 2007 FDA Amended Complaint, the Clarion S-Series C1.2 and HiRes90k devices were defective, adulterated, misbranded, unreasonably unsafe, and had a propensity to fail when implanted. In addition, Defendants Advanced Bionics knew, or reasonably should have known, that they had an obligation to investigate and to promptly inform the FDA, healthcare providers, and/or Advanced Bionics cochlear implant recipients, including J.R., of the failures, risks, and dangers associated with the devices.

331. Defendants Advanced Bionics breached their duty by failing to reasonably warn the Reid family and J.R.'s healthcare providers that his Clarion S-Series C1.2 and/or HiRes 90k devices were potentially defective before the devices were implanted and to exercise due care under the circumstances to prevent injury to Plaintiffs, including in failing to comply with federal requirements to take prompt corrective action when nonconforming devices were first discovered.

332. Had Defendants Advanced Bionics warned the Reid family of the defects and potential adverse consequences of implanting the Clarion S-Series C1.2 and/or HiRes 90k devices, the Reid family would never have allowed the devices to be implanted.

333. As a direct and proximate result of Defendants Advanced Bionics' failure to warn, Plaintiffs suffered serious injuries as herein alleged.

334. Defendants Advanced Bionics had specific knowledge of the unusually high rate of device failures, that the devices were not tested or validated in accordance with federal law, and that the devices were adulterated, prior to the date that J.R.'s implants were surgically

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implanted. Defendants Advanced Bionics' conduct, as set forth therein, was done with fraud and/or malice, and in conscious, willful, and reckless disregard of J.R.'s health, safety, and welfare. Thus, Plaintiffs are entitled to recover punitive damages.

SIXTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

335. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiff's Complaint as it set forth fully herein.

336. At all times relevant to this action, on and prior to the implant of the Clarion S-Series C1.2, Defendants Advanced Bionics utilized advertising media, professional publications, and sales representatives to urge the use, purchase, and implantation of the Clarion S-Series C1.2 cochlear implant devices, and expressly warranted to members of the general public, including J.R. and his healthcare providers, that the Clarion S-Series C1.2 was "free from defects in workmanship and materials and will not fail in the environment of the human body for a period of 10 years from the date of implantation."

337. The Reid family relied upon the said express warranties of Defendants Advanced Bionics in the purchase, use, and implantation of the Clarion S-Series C1.2 cochlear implant device.

338. J.R.'s Clarion S-Series C1.2 was not effective, proper, and safe for its intended use as expressly warranted by Defendants Advanced Bionics in that the Clarion S-Series C1.2 cochlear implant device was defective and caused serious injury to J.R. when it was put to its intended use.

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339. At all times relevant to this action, on and prior to the implant of the HiRes 90k devices, Defendants Advanced Bionics utilized advertising media, professional publications, and sales representatives to urge the use, purchase, and implantation of the HiRes 90k cochlear implant devices, and expressly warranted to members of the general public, including J.R. and his healthcare providers, that the HiRes 90k was "free from defects in workmanship and materials and will not fail in the environment of the human body for a period of 10 years from the date of implantation."

340. Plaintiffs relied upon the said express warranties of Defendants Advanced Bionics in the purchase, use, and implantation of the HiRes 90k cochlear implant devices.

341. J.R.'s HiRes 90k cochlear implant devices were not effective, proper, and safe for their intended use as expressly warranted by Defendants Advanced Bionics in that the HiRes 90k cochlear implant devices were defective and caused serious injury to J.R. when they were put to their intended use.

342. Defendants Advanced Bionics failed to provide cochlear implants to J.R. that were not defective.

343. As a direct and proximate result of Defendants Advanced Bionics' breach of their express warranties, Plaintiffs suffered serious injuries as herein alleged.

344. Defendants Advanced Bionics had specific knowledge of the unusually high rate of device failures, that the devices were not tested or validated in accordance with federal law, and that the devices were adulterated, prior to the date that J.R.'s implants were surgically implanted. Defendants Advanced Bionics' conduct, as set forth therein, was done with fraud and/or malice, and in conscious, willful, and reckless disregard of J.R's health, safety, and welfare. Thus, Plaintiffs are entitled to recover punitive damages.

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SEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

345. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

346. Defendants impliedly warranted that the HiRes90k Device, which Defendants designed, manufactured, assembled, promoted and sold to the Reid family, was merchantable and fit and safe for ordinary use.

347. Defendants further impliedly warranted that their Device, which Defendants designed, manufactured, assembled, promoted and sold to the Reid family, was fit for their particular purposes.

348. As a result of a manufacturing defect and violations of applicable CGMP requirements, Defendants' Device was defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected J.R. to severe and permanent injuries and/or death.

349. Defendants breached the implied warranties of merchantability and fitness for a particular purpose when their Device was sold to the Reid family, in that the Devices were defective and suffered water leaks and, therefore, failed to function.

350. Any purported written warranty fails of its essential purpose.

351. Any disclaimers of implied warranties are ineffectual to the extent not provided to or otherwise made known to the Reid family.

352. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and personal injury to the Reid family in that it, in effect, provides no remedy at all for the defect necessary to be redressed.

353. Any such disclaimer of consequential damages is unconscionable.

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354. As a direct and proximate result of Defendants' breach of implied warranties, the Reid family has sustained economic losses and other damages for which the Reid family is entitled to compensatory and equitable damages in an amount to be proven at trial.

355. Defendants had specific knowledge of the unusually high rate of device failures, that the devices were not tested or validated in accordance with federal law, and that the devices were adulterated, prior to the date that J.R.'s implants were surgically implanted. Defendants Advanced Bionics' conduct, as set forth therein, was done with fraud and/or malice, and in conscious, willful, and reckless disregard of the Reid family's health, safety, and welfare. Thus, Plaintiffs are entitled to recover punitive damages.

EIGHTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF FITNESS

356. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiff's Complaint as if set forth fully herein.

357. At the time Defendants Advanced Bionics designed, manufactured, marketed, produced, inspected, tested, packaged, warranted, distributed, sold, supplied, and otherwise placed cochlear implants into the stream of commerce for use by Plaintiffs, Defendants Advanced Bionics knew of the particular use for its cochlear implant devices, including the Clarion S-Series C1.2 and HiRes 90k devices sold to and implanted in J.R.

358. Plaintiffs and/or J.R.'s healthcare providers relied on Defendants Advanced Bionics' skill and judgment to furnish suitable goods.

359. At the time it left Defendants Advanced Bionics' hands and was implanted into J.R., the Clarion S-Series C1.2 cochlear implant device was not "suitable goods" and was neither reasonably safe nor minimally safe for its particular use.

360. At the time they left Defendants Advanced Bionics' hands and were implanted into J.R., the HiRes 90k cochlear implant devices were not "suitable goods" and were neither reasonably safe nor minimally safe for their particular use.

361. As a direct and proximate result of Defendants Advanced Bionics' breach of implied warranty of fitness for a particular purpose, Plaintiffs suffered serious injuries as herein alleged.

362. Defendants had specific knowledge of the unusually high rate of device failures, that the devices were not tested or validated in accordance with federal law, and that the devices were adulterated, prior to the date that J.R.'s implants were surgically implanted. Defendants Advanced Bionics' conduct, as set forth therein, was done with fraud and/or malice, and in conscious, willful, and reckless disregard of the Reid family's health, safety, and welfare. Thus, Plaintiffs are entitled to recover punitive damages.

NINTH CAUSE OF ACTION

FRAUD

363. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiff's Complaint as it set forth fully herein.

364. Defendants expressly, impliedly, falsely and fraudulently represented to members of the general public, including the Reid family and the Reid family's health care providers, that the HiRes 90k devices were of merchantable quality, in compliance with federal law and regulations, not adulterated, not misbranded, and safe for the use for which they were intended. These misrepresentations and omissions of fact include, but are in no way limited to:

a. Defendants never disclosed to the Reid family or the Reid family's physicians that it did not supplement its PMA Application to include the AstroSeal feed-thru.

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b. Defendants never disclosed to the Reid family or the Reid family's physicians or audiologists that it did not test the HiRes 90k device in a simulated environment in which the device was to be implanted (i.e. the human body) before commencement of marketing the device.

c. Defendants never disclosed to the Reid family or the Reid family's physicians and audiologists that it had surreptitiously commenced life cycle testing in an environment which simulated the human body in 2004, and within 70 days, 50% of the test devices failed such testing.

d. Defendants never disclosed to the Reid family or the Reid family's physicians that there was a history of device failures related to moisture with the Clarion and Clarion II, Defendants' previous cochlear implant devices.

e. Defendants made representations via comments to the Reid family and/or the Reid family's physicians through oral representations and/or written promotional and marketing materials that its products were the most technologically advanced and the safest.

f. Defendants failed to tell the Reid family that it knew HiRes90k devices were leaking at the feedthru, which the company knew as late as October 2004.

365. The following facts were true as of the date that J.R. was implanted with the HiRes90k Device in his left ear in September 3, 2004:

a. The HiRes90k was not tested before marketing in an environment that simulated the human body.

b. Defendants declared that they would not wait for all risks to be studied before selling the device that J.R. received.

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c. The FDA had previously cited Advanced Bionics in a Form 483 in 2001 for failing to submit PMA applications for manufacturing processes and design changes.

d. There were more than 100 devices that failed for leaking in predecessor generation devices.

e. Of the devices leaking, Advanced Bionics was aware by May 2002 that devices were leaking, among other places, through the feedthru (the same component where J.R.'s device leaked).

f. A "Hermeticity Task Team" was set up by Defendants to solve the "major problems" of leaking with Advanced Bionics cochlear implant.

g. Advanced Bionics engineers admitted that there was "not enough data to determine how reliable the AstroSeal feedthrus would be" in January 2003.

h. There was a problem with the "seal fixture" in the HiRes90k using AstroSeal feedthrus in February 2003.

i. There was knowledge that the hermeticity problems Advanced Bionics was experiencing with PA&E devices was applicable to AstroSeal, as well, before J.R. was implanted.

j. Advanced Bionics admitted in April 2003, before J.R. was implanted, that it would not know the "long term effectiveness" of the HiRes90k feedthru for "years."

k. In June 2004, one-third of devices tested at a third party vendor had high moisture.

366. In addition to the facts listed in the preceding paragraph concerning Advanced Bionics' actions as of September 3, 2004, the following was also true as of the date that J.R. was implanted with the HiRes90k Device in his right ear on September 7, 2005:

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a. The former majority owner told Advanced Bionics employees to stop testing returned devices in August/September 2004.

b. The FDA performed a "for cause" inspection because of device reliability concerns in August/September 2004.

c. Advanced Bionics engineers, including the designer of the HiRes90k, informed company management that devices were leaking, including through the feedthru, and that company investigations into the issue were being mishandled.

d. The FDA issued a Warning Letter in February 2005.

e. The auditory division president advised company leaders on a Saturday night in February 2005 that devices were continuing to fail at an alarming rate.

f. Advanced Bionics received a "post fix" returned device with high moisture in March 2005, thus giving the company notice that the problem was not with sealing in moisture but instead leaking.

g. The President of Operations told a group of Advanced Bionics employees that "hitting the numbers" (i.e. sales) was more important than quality.

h. Advanced Bionics' shareholders were being paid a bonus for the number of devices sold, and such a figure was not benchmarked on quality.

i. Advanced Bionics did not do its job in qualifying the AstroSeal feed-thru.

367. Defendants knowingly or recklessly made material false representations to the Reid family and the Reid family's healthcare providers about the functionality of the HiRes 90k Device with the intent that the Reid family would act and/or refrain from acting on its representations.

368. The Reid family and the Reid family's health care providers relied upon said representations of Defendants in the selection, purchase, and use of the HiRes 90k device, and

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but for the falseness of those representations, implantation would not have occurred and/or J.R.'s defective Device would have been removed much earlier.

369. Said representations by Defendants were false and untrue, in that the HiRes 90k devices were not in compliance with federal safety regulations and laws, were adulterated, were not safe for their intended use, nor were they of merchantable quality or functional devices as represented by Defendants. Defendants were aware that the devices had very dangerous properties and defects that could potentially cause injury and damage to the users of the HiRes90k devices, including J.R., thereby threatening the health, life, and hearing of J.R..

370. At all times relevant to this action, prior to and at the time Defendants sold the devices and while they were surgically implanted, Defendants knew, as a result of complaints of other users, explant tests, research and other information, that the HiRes 90k devices, and their component parts, were defectively designed and/or manufactured, adulterated, and in violation of federal safety regulations and laws in that they had extremely dangerous properties and defects.

371. Defendants further knew that the devices had a propensity to stop functioning properly and/or completely fail, while implanted, from exposure to moisture and from other causes.

372. At all times relevant to this action, Defendants, despite the actual knowledge described herein above, intentionally suppressed the aforementioned test results, complaints, and other information to keep such knowledge from the general public, including the Reid family and the Reid family's health care providers.

373. Defendants included a Package Insert with the HiRes90k devices implanted in J.R. That insert stated that the device had been exposed to clinical trials. The insert provided graphs and explanations of the failure rate of the device.

374. The clinical trial information provided in the Package Insert related to the HiRes90k with a PA&E feedthru.

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375. No clinical trials were performed on the device in the package, namely the HiRes90k with an AstroSeal feedthru.

376. The statements made in the Package Insert were untrue, in that the device enclosed with the insert had not been subjected to any clinical trials, nor were failure rates for any clinical trials known for the HiRes90k with an AstroSeal feedthru.

377. Defendant Advanced Bionics sent a letter to clinicians on September 27, 2004, informing them of the recall of HiRes90k devices.

378. The September 27, 2004 letter claims that HiRes90k devices have failed and a recall is necessary due to "moisture within devices as they are produced."

379. In reality, the source of moisture in HiRes90k devices was external. HiRes90k devices had a leak path through the defective AstroSeal feedthru, rather than a problem with sealed-in moisture.

380. Prior to September 2004, Advanced Bionics had tested the theory that their manufacturing processes were causing "moisture within the devices as they are produced." Tests had shown that moisture was not being sealed in the devices. Advanced Bionics' Manager of Auditory Quality stated that these tests "lay to rest any concern about the adequacy of the vacuum bakeout conditions to remove liquid water added during the production sequence."

381. Statements in the September 27, 2004 letter regarding the source of moisture and the efficacy of corrective actions being taken by Defendants were false.

382. As a result of Defendants' conduct and the Reid family's detrimental reliance on the same, the Reid family has sustained and will continue to sustain physical injuries, emotional distress, economic losses and other damages for which the Reid family is entitled to damages.

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TENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

383. Plaintiffs repeat, reallege and incorporate herein by this reference all of the preceding allegations as though set forth in full.

384. Defendants Advanced Bionics negligently misrepresented to members of the general public, including Plaintiffs and the Reid family's healthcare providers, that the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices were of merchantable quality, in compliance with federal laws and regulations, not adulterated, not misbranded, and safe for the use for which they were intended.

385. Plaintiffs and/or the Reid family's healthcare providers reasonably relied, to their detriment, upon the misrepresentations and omissions of Defendants Advanced Bionics in their labeling, advertisements, and promotions concerning, inter alia, the safety, longevity, and effectiveness of the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices. They also relied on Defendants Advanced Bionics' representations that the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices were safe for use.

386. As a direct and proximate result of Defendants Advanced Bionics' conduct and Plaintiffs' detrimental reliance thereon, Plaintiffs suffered serious injuries as herein alleged.

387. Defendants had specific knowledge of the unusually high rate of device failures, that the devices were not tested or validated in accordance with federal law, and that the devices were adulterated, prior to the date that J.R.'s implants were surgically implanted. Defendants Advanced Bionics' conduct, as set forth therein, was done with fraud and/or malice, and in conscious, willful, and reckless disregard of the Reid family's health, safety, and welfare. Thus, Plaintiffs are entitled to recover punitive damages.

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ELEVENTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

388. Plaintiffs repeat, reallege and incorporate herein by this reference all of the preceding allegations as though set forth in full.

389. Defendants Advanced Bionics intentionally and purposefully concealed material information from healthcare providers, the FDA, and patients concerning the defective nature and danger of the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices, including information that the devices were not as safe as other similar cochlear implant devices, that the devices were not of merchantable quality, that the devices were not in compliance with federal laws and regulations, that the devices were adulterated, that the devices were misbranded, that the devices were not safe for the use for which they were intended, that the devices were defective, and that the devices posed a dangerous risk to consumers. In doing so, Defendants Advanced Bionics acted with willful, wanton, and reckless disregard for the safety of consumers.

390. Defendants Advanced Bionics purposefully and intentionally concealed material information that would have caused healthcare providers and consumers to know that their prior representations concerning the superiority, effectiveness, safety, longevity, and merchantability of the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices were false,

391. Plaintiffs and/or the Reid family's healthcare providers relied on the representations made by Defendants Advanced Bionics concerning the superiority, effectiveness, safety, longevity, and merchantability of the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices. They further depended and relied on Defendants Advanced Bionics to inform them of information tending to indicate that the cochlear implant devices were defective and/or that there were serious dangers associated with the implantation and continued use of the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices. Absent disclosure by Defendants Advanced Bionics, Plaintiffs had no way to know the truth as to the cause of J.R.'s problems.

392. As a direct and proximate result of Defendants Advanced Bionics' fraudulent concealment, Plaintiffs and/or the Reid family's healthcare providers were unaware of the latent

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dangers posed by the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices and were unaware that the defective devices were the cause of J.R.'s pain and regression in hearing and speech.

393. As a direct and proximate result of Defendants Advanced Bionics' fraudulent concealment, Plaintiffs suffered serious injuries as herein alleged.

394. Defendants had specific knowledge of the unusually high rate of device failures, that the devices were not tested or validated in accordance with federal law, and that the devices were adulterated, prior to the date that J.R.'s implants were surgically implanted. Defendants Advanced Bionics' conduct, as set forth therein, was done with fraud and/or malice, and in conscious, willful, and reckless disregard of J.R.'s health, safety, and welfare. Thus, Plaintiffs are entitled to recover punitive damages.

TWELFTH CAUSE OF ACTION

DECEPTIVE BUSINESS PRACTICES UNDER GENERAL BUSINESS LAW §349

395. Plaintiffs repeat, reallege and incorporate herein by this reference all of the preceding allegations as though set forth in full.

396. Defendants Advanced Bionics expressly, impliedly, falsely, and fraudulently represented to members of the general public, including Plaintiffs and the Reid Family's healthcare providers, that the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices were of merchantable quality, in compliance with federal laws and regulations, not adulterated, not misbranded, and safe for the use for which they were intended.

397. Plaintiffs and the Reid Family's healthcare providers relied upon said representations of Defendants Advanced Bionics in the selection, purchase, use, and implantation of the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices, and but for the falseness of those representations, implantation would not have occurred and/or J.R.'s defective devices would have been removed much earlier.

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398. At all times relevant to this action, Defendants Advanced Bionics, despite the actual knowledge described herein above, intentionally suppressed the aforementioned test results, complaints, and other information to keep such knowledge from the general public, including Plaintiffs and J.R.'s healthcare providers.

399. Defendants Advanced Bionics' misrepresentations, along with their failure to warn and concealment of material information indicating that the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices were defective and dangerous, constituted an act or practice that was deceptive or misleading in a material way.

400. As a direct and proximate result of Defendants Advanced Bionics' deceptive business practices and Plaintiffs' detrimental reliance thereon, Plaintiffs suffered serious injuries as herein alleged.

401. As a direct and proximate result of Defendants Advanced Bionics' deceptive business practices, Plaintiffs and/or J.R.'s healthcare providers were unaware of the latent dangers posed by the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices and were unaware that the defective devices were the cause of J.R.'s pain and regression in hearing and speech.

402. Defendants had specific knowledge of the unusually high rate of device failures, that the devices were not tested or validated in accordance with federal law, and that the devices were adulterated, prior to the date that J.R.'s implants were surgically implanted. Defendants Advanced Bionics' conduct, as set forth therein, was done with fraud and/or malice, and in conscious, willful, and reckless disregard of J.R.'s health, safety, and welfare. Thus, Plaintiffs are entitled to recover punitive damages.

THIRTEENTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

403. Plaintiffs repeat, reallege and incorporate herein by this reference all of the preceding allegations as though set forth in full.

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404. Defendants Advanced Bionics falsely and fraudulently represented to the medical and healthcare community, to Plaintiffs, and to the public generally that the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices were clinically safe and/or effective.

405. The representations made by Defendants Advanced Bionics were, in fact, false.

406. When said representations were made by Defendants Advanced Bionics, they knew those representations to be false, and acted with willful, wanton, and reckless disregard for the safety of consumers of the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices.

407. The representations were made by Defendants Advanced Bionics with the intent of defrauding and deceiving the medical community into recommending and prescribing the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices and deceiving patients, including Plaintiffs, into purchasing and consenting to the implantation of the devices.

408. At the time the aforesaid representations were made by Defendants Advanced Bionics and the time that J.R. was implanted with the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices, Plaintiffs and/or J.R.'s healthcare providers were unaware of the falsity of said representations and reasonably believed them to be true.

409. As a direct and proximate result of Defendants Advanced Bionics' deceptive business practices and Plaintiffs' detrimental reliance thereon, Plaintiffs suffered serious injuries as herein alleged.

FOURTEENTH CAUSE OF ACTION

UNJUST ENRICHMENT

410. Plaintiffs repeat, reallege and incorporate herein by this reference all of the preceding allegations as though set forth in full.

411. As the intended and expected result of their wrongdoing, Defendants Advanced Bionics have profited and benefited from the purchase of the Clarion S-Series C1.2 and HiRes 90k cochlear implant devices by Plaintiffs. Defendants Advanced Bionics have also profited from the HiRes 90k cochlear implant device used in the revision of J.R.'s cochlear implant.

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412. Defendants Advanced Bionics have voluntarily accepted and retained these profits, knowing that as a result of their negligence and fraud, J.R. did not receive a reasonably safe product, and his parents were caused to incur additional expenses in replacing the defective cochlear implants.

413. By virtue of the wrongdoing alleged herein, Defendants Advanced Bionics have been unjustly enriched at the expense of Plaintiffs, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants Advanced Bionics' wrongful profits, revenues, and benefits, and such other relief as is proper to remedy Defendants Advanced Bionics' unjust enrichment.

FIFTEENTH CAUSE OF ACTION

FALSE ADVERTISING IN VIOLATION OF GENERAL BUSINESS LAW §350

414. Plaintiffs repeat, reallege and incorporate herein by this reference all of the preceding allegations as though set forth in full.

415. The representations, actions, and omissions of Defendants set forth above constitute intentional false advertising.

416. As a result of Defendants' false advertising, Plaintiffs suffered serious injuries as herein alleged.

SIXTEENTH CAUSE OF ACTION

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

417. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

418. Defendants carelessly and negligently designed, manufactured, marketed, and sold the Device to the Reid family, carelessly and negligently concealed the defects in the Device from the Reid family, and carelessly and negligently misrepresented the quality, safety, and usefulness of the Device. Defendants knew or should have realized that such conduct involved

an unreasonable risk of causing emotional distress to reasonable persons that might, in turn, result in illness or bodily harm.

419. Defendants owed a duty to treating physicians, recipients of the Device, and families of the recipients, including the Reid family, to accurately and truthfully represent the risks of the Device. Defendants breached that duty by misrepresenting and/or failing to adequately warn of the risks of the Device – effects of which Defendants knew or in the exercise of diligence should have known – to the treating physicians and the Reid family.

420. As a direct and proximate result of Defendants' wrongful conduct and breach of duty, J.R. has sustained and will continue to sustain severe emotional distress either due to physical injury or a rational fear of physical injury or death and is entitled to recovery of damages in an amount to be proven at trial. Defendants are liable to the Reid family for all general, special and equitable relief to which Plaintiff is entitled by law.

SEVENTEENTH CAUSE OF ACTION

INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

421. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

422. Defendants' conduct directed towards the Reid family was, by act and omission, intentional, knowing, and/or reckless, and evidence a willful intention to inflict injury upon Plaintiff, or a reckless disregard for the rights and interests of the Reid family equivalent to an intentional violation of them. This conduct exceeded all bounds usually tolerated by decent and civilized society and was directed toward an inherently vulnerable population of persons with profound hearing loss.

423. As a direct, proximate, intended, known, natural, and foreseeable result of Defendants' conduct, the Reid family was and is suffering injury in the form of serious, severe, extreme and/or disabling emotional distress that no reasonable person could or should be expected to endure.

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424. Defendants are liable and accountable at law to compensate the Reid family for such emotional distress, and for all such damages and injuries resulting therefrom and related thereto.

425. Defendants' conduct was intentional, knowing, oppressive, fraudulent, malicious, extreme and outrageous, and done in conscious and reckless disregard of the Reid family's rights, thereby entitling the Reid family to assert claims for exemplary and punitive damages, at the appropriate time under governing law, in an amount sufficient, necessary and appropriate to punish Defendants for their reprehensible conduct and to deter them and others from such conduct in the future. Defendants are liable to the Reid family for all general, special and equitable relief to which Plaintiff is entitled by law.

EIGHTEENTH CAUSE OF ACTION

DERIVATIVE CLAIMS OF PARENTS

426. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

427. At all relevant times, Plaintiffs David and Corinne Reid were the lawful parents of J.R.

428. As J.R.'s parents, David and Corinne Reid are entitled to J.R.'s society, companionship, love, affection, and services and are liable for his medical and other expenses.

429. Plaintiffs David and Corinne Reid were, are, and will be deprived of J.R.'s society, companionship, love, affection, and services, and have been and will be compelled to spend money for J.R.'s medical and other expenses, and thus have been damaged.

PUNITIVE DAMAGES ALLEGATIONS

430. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

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431. The wrongs done by Defendants were aggravated by malice, fraud, and reckless disregard for the rights of others, the public, and the Reid family.

432. Defendants were actually, subjectively aware of the risk involved in continuing to market the Device despite having failed to ensure that the Device would not leak and cease to function from excessive moisture, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of patients, including J.R.

433. The Reid family asserts claims for exemplary and punitive damages in an amount allowed that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future

434. The Reid family alleges that the conduct of multiple employees, officers, and managing agents of Defendants constituted malice, oppression, and/or fraud in that these persons willfully marketed, sold, and allowed implantation of thousands of patients with a knowing disregard of the rights or safety of those patients, a device which was adulterated, untested, and not fit for its intended purpose.

435. The Reid family alleges that Defendants' conduct was fraudulent in that there was an intentional misrepresentation that the HiRes90k device had been properly tested prior to marketing as well as a concealment post-marketing of a 50% failure rate when the devices were belatedly tested.

436. Plaintiff alleges that the conduct of the Defendants was "despicable" in that the conduct was motivated by monetary gain of the participants.

437. Plaintiff alleges that the misconduct of the Defendants was the direct, proximate and legal cause of the injuries sustained by the Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

(a) to enter judgment in favor of Plaintiff and against Advanced Bionics on all causes of action as alleged in the Complaint;

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(b) to award compensatory damages and restitution in an amount to be ascertained at trial;

(c) for preliminary and permanent injunctive relief;

(d) to award punitive damages to Plaintiff in an amount to be ascertained at trial;

(e) to award costs of suit, including attorney fees and interest as permitted by law; and

(f) to enter such other and further relief as the Court may deem just under the circumstances.

JURY DEMAND

Plaintiff hereby demands a jury trial on all issues so triable.

DATED the 19th day of February, 2013.

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